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CONTRACTING ORGANIZATION: Georgetown University
Washington, DC 20057

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13. ABSTRACT (Maximum 200 Words)

This project is aimed at improving the state of the art of image-guided and minimally invasive spine procedures by developing a new generation of clinical techniques along with the computer-based hardware and software needed for their implementation. The current focus of the project is on physician assist systems incorporating robotics, tracking, and visualization to improve the precision of instrument placement and manipulation in minimally invasive procedures.

Key research accomplishments for this year are:
- Completed a cadaver study showing the ability of a physician to use a joystick controlled "needle driver" robot to hit BB targets in the spine
- Received an FDA Investigational Device Exemption (IDE) for a clinical trial to use the robot for perispinal nerve and facet blocks
- Developed a liver respiratory motion simulator to demonstrate the feasibility of using magnetic tracking for precision minimally invasive liver interventions
- Establish a new collaboration with the Department of Radiology in the NIH Clinical Center to investigate the use of magnetic tracking for radiofrequency ablation
- Established a new collaboration with the National Capital Area Medical Simulation Center of the Uniform Services University of the Health Sciences and the Space Systems Laboratory of the University of Maryland to investigate a low-cost force feedback device for surgical simulation

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3 Table of Contents

4　Introduction

This project is aimed at improving the state of the art of image-guided and minimally invasive spine procedures by developing a new generation of clinical techniques along with the computer-based hardware and software needed for their implementation. The current focus of the project is on physician assist systems incorporating robotics, tracking, and visualization to improve the precision of instrument placement and manipulation in minimally invasive procedures. The project is led by the Imaging Sciences and Information Systems (ISIS) Center of the Department of Radiology at Georgetown University and project collaborators include the Department of Radiology at Walter Reed Army Medical Center, the Urology Robotics Group at Johns Hopkins Medical Institutions, and the NSF sponsored Engineering Research Center for Computer Integrated Surgical Systems and Technology at Johns Hopkins University.

5　Report Body

This section describes the research accomplishments associated with each task in the statement of work. This is the third year report and includes research performed from 01 January 2001 to 31 December 2001. The award number is DAMD17-99-1-9022.

5.1 Task 1: Program Planning and Management

Program planning and management continues to focus on the direction of the project as well as relationships with project collaborators. Project planning and review meetings are held monthly at the ISIS Center, and it is the consensus that the current focus on physician assist systems for the next generation interventional suite is an appropriate direction. In the 2001 calendar year major progress was made on our hardware testbeds including delivery of the robot and development of a liver respiratory motion simulator. The focus is now on evaluating these testbeds in the clinical environment, namely the interventional suite at Georgetown.

We have continued our very close cooperation with both the Urology Robotics Group at Johns Hopkins Medical Institutions (lab director Dan Stoianovici, PhD) and the NSF sponsored Engineering Research Center for Computer Integrated Surgical Systems and Technology at Johns Hopkins University (center director Russell Taylor, PhD). The Urology Robotics Group delivered our needle driver robot in August and this system was used in cadaver studies in September. The system was brought to TATRC in September as well for a demonstration and presentation by Dr. Cleary. The Engineering Research Center has continued to work with us to develop the robot biopsy testbed. Dr. Cleary also attended their strategic planning meeting this fall and we are continuing our financial support of one of their PhD students. Since there is no Engineering School at Georgetown University, this provides the project with a graduate student to help develop the algorithms and software for this testbed. It also allows us to leverage off the extensive medical robotics program at Johns Hopkins University.

5.2 Task 2: Spinal Robotics

One of the key research outcomes of this reporting period has been the delivery of a "needle driver" robot from the Urology Robotics Laboratory at Johns Hopkins Medical Institutions. We have just received FDA approval for a clinical trial of this device for spinal nerve and facet blocks. While the protocol and consent form for this trial has been approved the Georgetown Institutional Review Board and the U.S. Army Human Subjects Board, there are some minor changes that have been suggested to the consent form that are still awaiting final approval. Once this approval has been obtained, the clinical trial can begin and we hope to do so this spring. Our FDA approval is for an initial 20 patients, with the potential for 100 patients after the initial data has been reviewed. A copy of our FDA Investigational Device Exemption (IDE) application is included in the appendix as Section 10.5.

A picture of the robotic device is shown in Figure 1[1]. The device consists of:
1) A mechanical arm that can be positioned at any location above the patient's spine.
2) A touch screen and joystick through which the operator can control the device.
3) A mounting base that attaches the device to the interventional table.

The robot was delivered in August, and a cadaver study was completed on 1 September 2001. The cadaver study is described in the report "Robotically Assisted Perispinal Nerve and Facet Blocks: A Cadaveric Study" [Cleary 2001b][2]. The purpose of the study was to evaluate the feasibility of using a joystick controlled robotic needle driver to place a 22-gauge needle for perispinal nerve and facet blocks. The interventional neuroradiologist from Georgetown was Vance Watson, MD. Bi-plane fluoroscopy and a robotic needle driver were used to place 12 needles into the lumbar perispinal region of a 98 year-old female embalmed cadaver. All needles were placed within 3 mm of the target BB. The average placement accuracy was 1.44 mm and the standard deviation was 0.66 mm. The conclusion was that a robotic needle driver can be used to accurately place needles in the nerve and facet regions.

This cadaver study has positioned us well for our clinical trial. While we await the final approval, we have been working with the Urology Robotics Laboratory to develop a "fluoroscopy servoing" capability for the device. The term "fluoroscopy servoing" means the robot is controlled based on feedback from the fluoroscopy images themselves, potentially without human intervention. For example, during spinal nerve and facet blocks, the physician may want the robot to align the needle directly with the C-arm of the fluoroscopy system. This can be done by "frame grabbing" the fluoroscopy image using a commercially available frame grabber board which has been integrated with the robot controller. This is one step towards our vision of the "Interventional Suite of the Future", in which physicians will indicate on the image themselves where they want their instruments to go and the instruments will be placed by robotic devices. The algorithms for aligning the needle are being developed by Mihai Mocanu, PhD, a visiting computer

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[1] All figures are in Section 10.1 which starts on page 13.
[2] All references are indicated by square brackets and listed in the reference section which is on page 12. Copies of papers and posters are in the appendices.

science professor from Romania. The user interface developed so far including a camera view from the frame grabber are shown in Figure 2. Dr. Mocanu is funded under this project and is jointly working at Georgetown and the Urology Robotics Laboratory at Johns Hopkins Medical Institutions. This collaboration has been invaluable for continued progress on this task.

As a related development to this project, Dr. Cleary was asked to edit a special issue of the journal *Computer Aided Surgery* focusing on Medical Robotics. This issue will appear soon as Volume 6, Number 6, 2001. A copy of Dr. Cleary's review article for this issue is in the appendix [Cleary 2001a].

5.3 Task 3: Robot Biopsy Testbed

In addition to the clinical protocol described in Task 2, we have also been developing a robot biopsy testbed. The goals of this testbed are 1) to compare robotically assisted biopsy to the current practice and 2) serve as a testbed for investigating software architectures for integrating robotics, tracking, and visualization. A system diagram is shown in Figure 3. The concept is further explained in the paper "CT-directed robot biopsy testbed: user interface and coordinate transformations" in the appendix [Cleary 2001d]. A poster showing the concept is also in the appendix [Cleary 2001g].

This task underwent a small change in focus this year. Previously, we had been developing our own software for the user interface and to control the robot and tracker. As part of our expanding partnership with the Engineering Research Center at Johns Hopkins University, it was decided to work with them to use the 3D Slicer as the user interface. The 3D Slicer is freely available, open-source software for visualization, registration, segmentation, and quantification of medical data. Development of the Slicer is an ongoing collaboration between the MIT Artificial Intelligence Lab and the Surgical Planning Lab at Brigham & Women's Hospital, an affiliate of Harvard Medical School.

Since the Surgical Planning Lab at Brigham & Women's Hospital is part of the Engineering Research Center at Johns Hopkins, this expands our project collaborators and allows us to leverage the work both groups have done to date on developing 3D Slicer. To date, we have been able to get 3D Slicer running on our robot controller. A view of the 3D Slicer user interface is shown in Figure 4. More information on 3D Slicer can be obtained from http://www.slicer.org/.

As part of this testbed, a novel method was developed for the automatic registration of a vertebral body using an optical tracker and embedded fiducial carrier. This method was tested on an interventional phantom (CIRS, Inc.) as shown in Figure 5. The fiducial carrier is manufactured by our tracking consultant, Neil Glossop, PhD, of Traxtal Technologies. The fiducial carrier contains 3 retro-reflective spheres (Figure 6) whose position can be tracked in real-time by the optical tracking system (hybrid Polaris, Northern Digital, Inc.). The fiducial carrier also contains 9 precisely spaced microspheres, which are small BBs approximately 1 mm in diameter (these cannot be seen in the figures). The microspheres appear as bright spot on the CT images and therefore their position in the CT coordinate system can be determined. Since we can also

determine the position of the microspheres with respect to the optical tracking system (the microspheres are at known locations relative to the 3 retro-reflective spheres), we can use this information to establish a coordinate transformation between the CT coordinate system and the optical tracker. Since a fiducial carrier is also attached to the robot, we can use this information to command the robot to go to a desired point in CT space. Note that this can all be done without operator intervention, and this is a step to the fully automated biopsy systems of the future. A one-page report on this technique was published in the Computer Aided Radiology and Surgery (CARS) 2001 conference [Cleary 2001c] and is included in the appendix. A poster on this topic is also included in the appendix [Cleary 2001e].

5.4 Task 4: Organ Tracking for Minimally Invasive Abdominal Interventional Procedures

The goal of this task is to investigate the use of magnetic tracking for precisely locating internal organs during interventional procedures. This is a collaboration with Northern Digital (Waterloo, Canada) and Traxtal Technologies (Houston, Texas). Northern Digital has been developing the AURORA™ magnetic tracking system, which enables instruments retrofitted with a sensing coil to be tracked and overlaid on an image of the anatomy. Our research group at Georgetown is serving as a beta test site and is one of the first research groups worldwide to receive this equipment. We have been developing an image-guided system for minimally invasive procedures that incorporates this technology. While image guidance using bony landmarks for procedures like pedicle screw insertion is now standard, a future challenge for the research community is to develop image guidance for internal organs.

The system is shown in Figure 7 and consists of a control unit, sensor interface device, and field generator as shown in the photograph on the left. The sensors (middle photograph) plug into the sensor interface unit and can be as small as 0.9 mm in diameter and 8 mm in length. For comparison, the sensor coil is shown next to a match with the leads protruding from the coil. According to a Northern Digital data sheet, the sensors have a positional accuracy of 1-2 mm and angular accuracy of 0.5-1 degree. The measurement volume (right photograph) is based on the reference coordinate system of the field generator. The distance along the x-axis is 280 to 640 mm, along the y-axis from –300 to 300 mm, and along the z-axis from –300 to 300 mm. This volume is sufficient to cover the area of interest for abdominal interventions.

To evaluate magnetic tracking for minimally invasive abdominal interventions, the Georgetown team has developed a liver respiratory motion simulator. The simulator includes a synthetic liver mounted on a one degree of freedom motion platform. Since most hepatic respiratory motion occurs in the cranio-caudal direction we felt this was a reasonable approximation. The linear motion platform is computer controlled, allowing physiologic respiratory patterns to be simulated. The simulator was first demonstrated at the Computer Aided Radiology and Surgery (CARS) Conference in Berlin, Germany, in June 2001. A block diagram of the simulator is shown in Figure 8. The simulator consists of a dummy torso, a synthetic liver model, a motion platform, a graphical user interface, the AURORA magnetic tracker system, and a magnetically tracked probe and catheter.

The simulator is described in more detail in [Cleary 2002]. In addition to this paper, a poster showing the simulator is also in the appendix [Cleary 2001f].

To test the system, a simulated transjugular intrahepatic portosystemic shunt (TIPS) procedure was carried out using a foam liver phantom and the respiratory motion simulator. The feasibility of this approach is discussed in [Banovac 2002]. A foam liver was cast with two barium coated straws and mounted to the one degree of freedom motion platform. A rib cage was taken from an anatomical model and placed over the moving liver. Fiducials were mounted on the rib cage (multi-modality radiographic markers, IZI Medical, Baltimore, MD). A special catheter, containing a magnetically tracked sensor coil, was inserted into the liver simulating the insertion of a coaxial catheter into the hepatic vein during the TIPS procedure. A pre-procedure CT scan was done (5 mm collimation with 1 mm reconstruction, 219 slices total). The scan was transferred to the image guidance software using the DICOM protocol. The desired path was then planned on the user interface by the interventional radiologist by selecting the skin entry and target points. The magnetic tracking system was then used to track the probe and provide image guidance.

Using the targeting window, the probe (actually a magnetic tracked needle) was placed on the skin entry point and then aligned along the desired trajectory. The targeting window consists of circles representing the tip and handle of the needle along with crosshairs indicating the target point. This interface was adopted as it felt that aligning the circles was easier than a direct anatomical view, particularly if the liver is moving. Similar targeting constructs have been proposed by other researchers. The needle was driven into the liver along this planned trajectory until the desired depth was indicated. The actual position of the needle was then confirmed by fluoroscopy as shown in Figure 9. Both "vessels" were successfully punctured with a single needle pass as can be seen in these images. This puncture would replace the difficult portosystemic venous puncture needed during a typical TIPS procedure.

The clinical lead on this project is Elliot Levy, MD, an interventional radiologist at Georgetown. Dr. Levy has been awarded a CIRREF Academic Transition grant (CIRREF is the Cardiovascular and Interventional Radiology Research and Education Foundation). This grant is to develop magnetic tracking technology for use in body interventional procedures in collaboration with Dr. Neil Glossop of Traxtal Technologies.

The project has also been greatly helped by a Radiology resident, Filip Banovac, MD, who has been doing a one-year research rotation at the ISIS Center. Dr. Banovac has received an NIH training grant and a research grant from the Radiology Society of North America (RSNA).

Finally, our work on magnetic tracking has led to a new collaboration with Brad Wood, MD, of the Department of Radiology at the NIH Clinical Center. Dr. Wood is interested in using magnetic tracking to aid in precision positioning for radiofrequency ablation of metastatic disease and related procedures. We have submitted a research proposal to NIH on this topic.

5.5 Task 5: Surgical Simulation

This task is a collaboration with the National Capital Area Medical Simulation Center of the Uniform Services University of the Health Sciences. A visiting researcher from Japan with a background in computer graphics has been hired (Daigo Tanaka, MS). Mr. Tanaka has worked part-time at the Simulation Center and part-time at the ISIS Center. From this collaboration, the Simulation Center submitted a proposal to develop a force feedback device for minimally invasive procedures to the National Medical Technology Testbed in Loma Linda, CA. Many surgical procedures involve the insertion of needles, guidewires, or catheters. While these procedures can be effectively taught using simulators, the development of simulation software is limited by the lack of a low-cost force feedback device. The goal here is to leverage technology developed by the gaming industry such as a force feedback joystick and adopt it for medical simulation.

This proposal is a collaboration between the Simulation Center, Georgetown University, and the University of Maryland. As of this report, the proposal was selected for funding. This is a new collaboration that came out of the Periscopic Spine Surgery project.

In addition, the simulation team developed and presented a tutorial on Medical Simulation at the SPIE Medical Imaging Conference in San Diego in February 2001. A copy of the introductory presentation given by Dr. Cleary is in the appendix in Section 10.6.

5.6 Task 6: Cancer Therapy

This is a spin-off from the original project. The goal of this task is to investigate how optimal dosing for chemotherapy might be enabled by combining disparate forms of medical data. A pilot project was begun in the summer of 2001 involving two professors from the Mathematics Department (Andrew Vogt, PhD, and Paul Kainen, PhD) and an oncologist from the Lombardi Cancer Center (John Marshall, MD). The aims of the pilot study were:
- To collect data and perform a pilot analysis of pharmacogenetic, clinical, and molecular tumor data from patients with liver metastases from colon cancer treated with Irinotecan (CPT-11).
- Through interactive discussion, to select from a group of available mathematical and statistical techniques several of the most promising for prediction of both tumor response and systemic toxicity.
- To apply the chosen statistical and mathematical methods to create a model predictive of both tumor response and systemic toxicity.

Data was collected from two ongoing clinical trials at Lombardi Cancer Center. Selected parameters such as white blood count, liver function tests, and toxicity events were put into an Excel spreadsheet to investigate possible correlations. A sample data set is shown in Figure 10. While the pilot project was useful for forming the research team and developing a study methodology, the amount of data available was not sufficient to draw statistically valid conclusions. The plans at the moment are to continue this project in the Summer of 2002.

5.7 Year 4 Plans

In year 4, the focus of the project will be on applying the testbeds developed to date on new interventional techniques. The clinical trial of nerve and facet blocks with the needle driver robot should begin. We plan to continue our research on magnetic tracking for abdominal interventions, first by completing the phantom studies and second by moving to animal studies. These studies should give us an idea of the role of these systems in the interventional suite of the future. We will also continue to look for new funding opportunities and synergistic collaborations.

5.8 Walter Reed Collaboration

As part of this project, we are collaborating with Walter Reed Army Medical Center to investigate new clinical techniques and technological developments for spine procedures. The primary collaboration is with the Department of Radiology, under the direction of Col. Michael Brazaitis, MD, Chairman, and Irwin Feuerstein, MD, EBCT Radiologist.

In the Department of Radiology, we have hired a consultant, Sharyn Greberman, ScD, MHS, to assist with our ongoing studies. Based on our previous efforts, approval of the protocol "Postmenopausal Coronary Artery Disease and Osteoporosis" was received in September 2001 from the Walter Reed Army Medical Center Department of Clinical Investigation. In October 2001, the first participant was enrolled. Interest in the study has been enormous, both on the parts of providers and of patients. To date, more than 50% of the sample has been enrolled and the remainder of the sample has scheduled their appointments. It is anticipated that the data set will be complete by April 2002 and analysis will begin.

QCT Pro is the bone densitometry software package being used to score the electron beam CT scans of the spines of the women in the study. Preliminary analysis indicates a correlation of greater than 93 percent between the T scores of the lumbar and thoracic spines of the participants. The same is true for the Z scores in these women. This is the primary research question addressed in this study. The investigators believe that additional information exists within this sample that provides the potential for other hypotheses to be addressed. These additional research questions will be developed further as the study progresses.

6 Key Research Outcomes

This section provides a bulleted list of key research accomplishments:

- Completed a cadaver study showing the ability of a physician to use a joystick controlled "needle driver" robot to hit BB targets in the spine

- Received an FDA Investigational Device Exemption (IDE) for a clinical trial to use the robot for perispinal nerve and facet blocks

- Developed a liver respiratory motion simulator to demonstrate the feasibility of using magnetic tracking for precision minimally invasive liver interventions

- Establish a new collaboration with Brad Wood of the Department of Radiology in the NIH Clinical Center to investigate the use of magnetic tracking for radiofrequency ablation
- Established a new collaboration with the National Capital Area Medical Simulation Center of the Uniform Services University of the Health Sciences and the Space Systems Laboratory of the University of Maryland to investigate a low-cost force feedback device for surgical simulation

7 Reportable Outcomes

This section provides a list of reportable outcomes.

The major product of this year is the list of manuscripts given in Section 10, References. Four conference papers were published or submitted, three poster presentations were made, and two journal articles were submitted. An FDA investigational device exemption (IDE) application was submitted and approved. A protocol for vertebral body motion tracking was also approved. A tutorial on Medical Simulation was created and presented. Copies of these documents are provided in the appendix.

In addition, four grant applications to the National Institutes of Health were submitted based on this work. A graduate student from Catholic University and a graduate student from Johns Hopkins University were supported during this year to assist in software development for the robotic biopsy testbed. The research group at Georgetown continued to take a lead in the Washington Area Computer Aided Surgery Society (www.washcas.org), which was formed in 2000 to promote research in the field.

8 Conclusions

The third year of work on the Periscopic Spine Surgery has continued to lay the groundwork for developing the physician assist systems of the future. These systems will incorporate robotics, tracking, and visualization to improve the precision of instrument placement and manipulation in minimally invasive procedures. The robot needle driver system was delivered and tested in a cadaver study. FDA approval for a clinical trial was received. A liver respiratory motion for investigating magnetic tracking was constructed. Collaborations with Johns Hopkins were strengthened and new collaborations were formed. The focus of the next year will continue to be on moving this technology to clinical practice to improve patient care.

9 References

[Banovac 2002]   Banovac F, Levy EB, Lindisch DJ, Pearce A, Onda S, Clifford M, "Feasibility of percutaneous transabdominal portosystemic shunt creation," accepted for publication in *Surgical and Radiologic Anatomy*, accepted Jan. 2002.

[Cleary 2002]   Cleary K, Banovac F, Levy E, Tanaka D, "Development of a liver respiratory motion simulator to investigate magnetic tracking for abdominal interventions," *SPIE Medical Imaging 2002: Visualization, Image-Guided Procedures, and Display*, San Diego, California, February 23-28, 2002.

[Cleary 2001a]   Cleary K, Nguyen C, "State of the art in surgical robotics: clinical applications and technology challenges," to be published in *Computer Assisted Surgery*, Volume 6, Number 6, 2001.

[Cleary 2001b]   Cleary K, Watson V, Lindisch D, "Robotically assisted perispinal nerve and facet blocks: a cadaveric study," unpublished manuscript, Oct. 2001.

[Cleary 2001c]   Cleary K, Xu S, Fichtinger G, Glossop N, "Automatic registration for percutaneous vertebral body tracking," *Computer Assisted Radiology and Surgery (CARS)*, Elsevier Press, 2001, page 1141.

[Cleary 2001d]   Cleary K, Onda S, Banovac F, Lindisch D, Glossop N, Jiang L, Xu S, Patriciu A, Stoianovici D, "CT-directed robot biopsy testbed: user interface and coordinate transformations," *Computer Assisted Radiology and Surgery (CARS)*, Elsevier Press, 2001, pages 171-177.

[Cleary 2001e]   Cleary K, Xu S, Fichtinger G, Glossop N, "Automatic registration for percutaneous vertebral body tracking," poster presented at the *Computer Assisted Radiology and Surgery (CARS) conference*, June 2001, Berlin, Germany.

[Cleary 2001f]   Cleary K, Banovac F, Levy E, Tanaka D, Onda S, Jiang L, Lindisch D, Corral G, "Respiratory liver motion simulator: a paradigm for percutaneous liver procedures using magnetic tracking," demonstration and poster presented at the *Computer Assisted Radiology and Surgery (CARS) conference*, June 2001, Berlin, Germany.

[Cleary 2001g]   Cleary K, Banovac F, Xu S, Fichtinger G, Stoianovici D, Glossop N, "CT-directed robotic biopsy testbed," poster presented at the Johns Hopkins University Engineering Research Center for the NSF site visit, January, 2001.
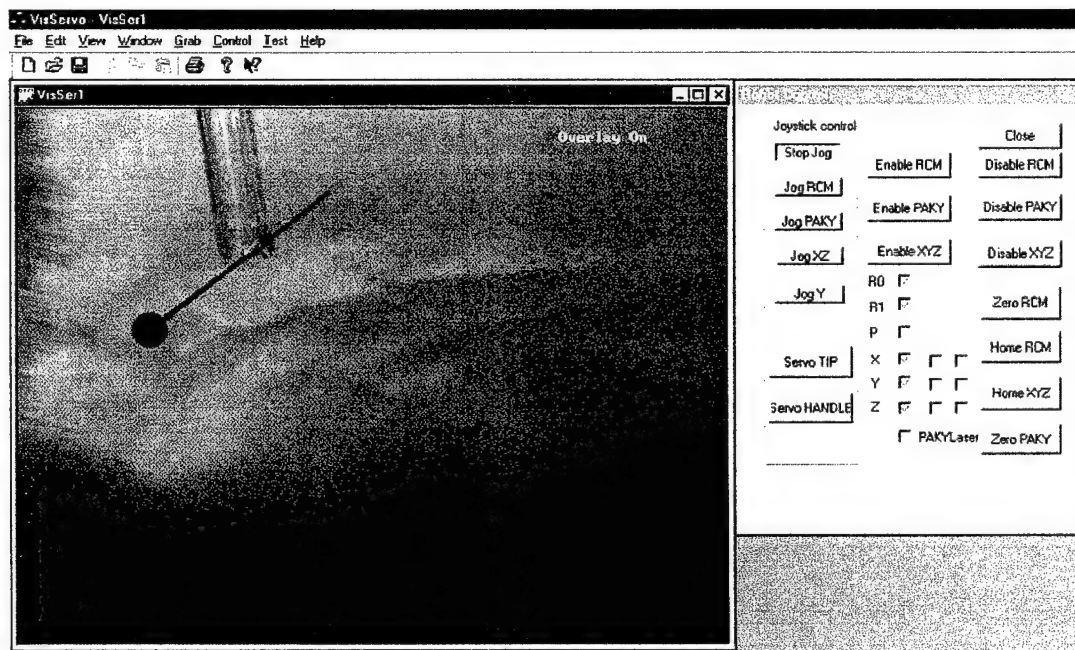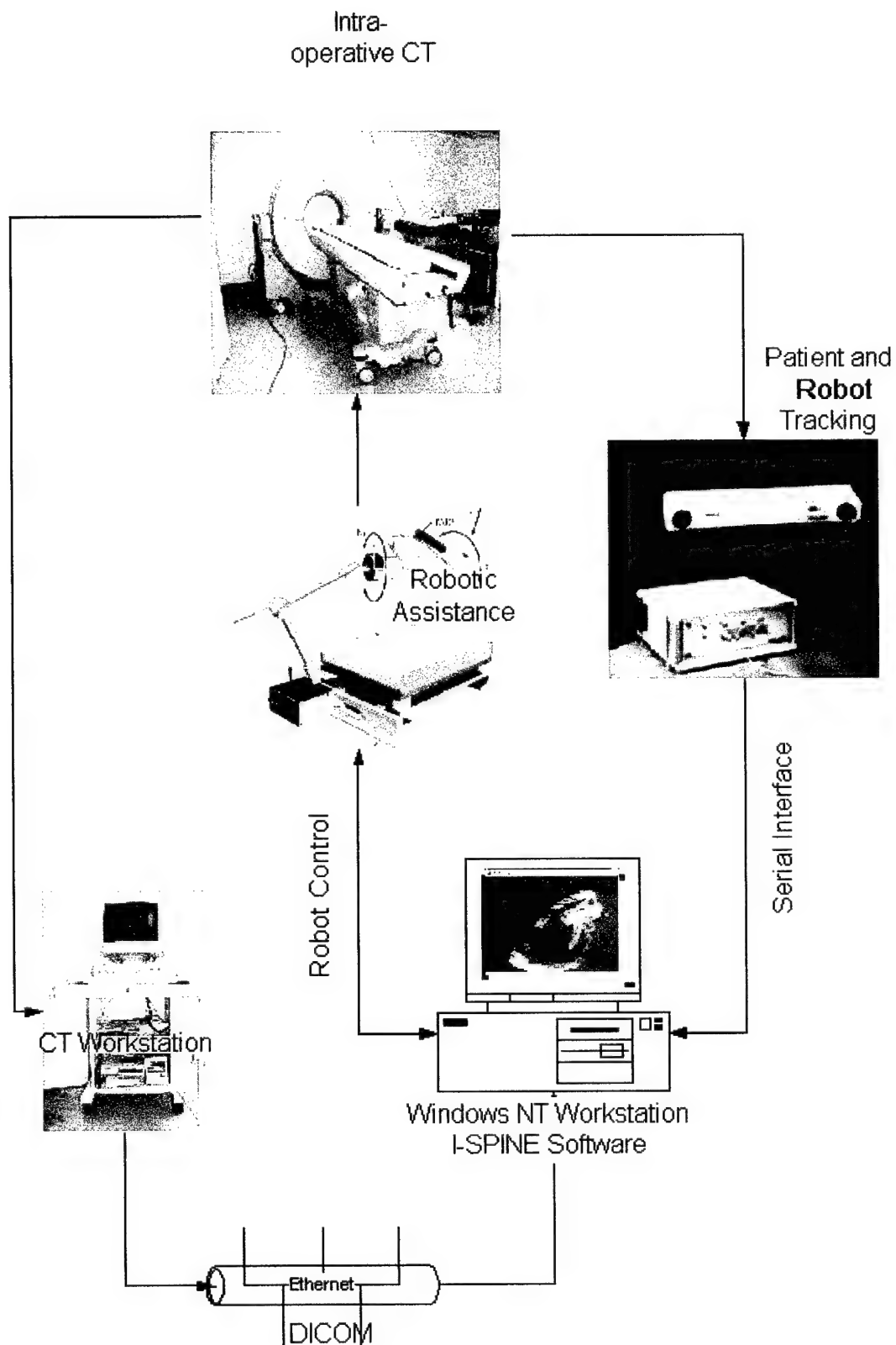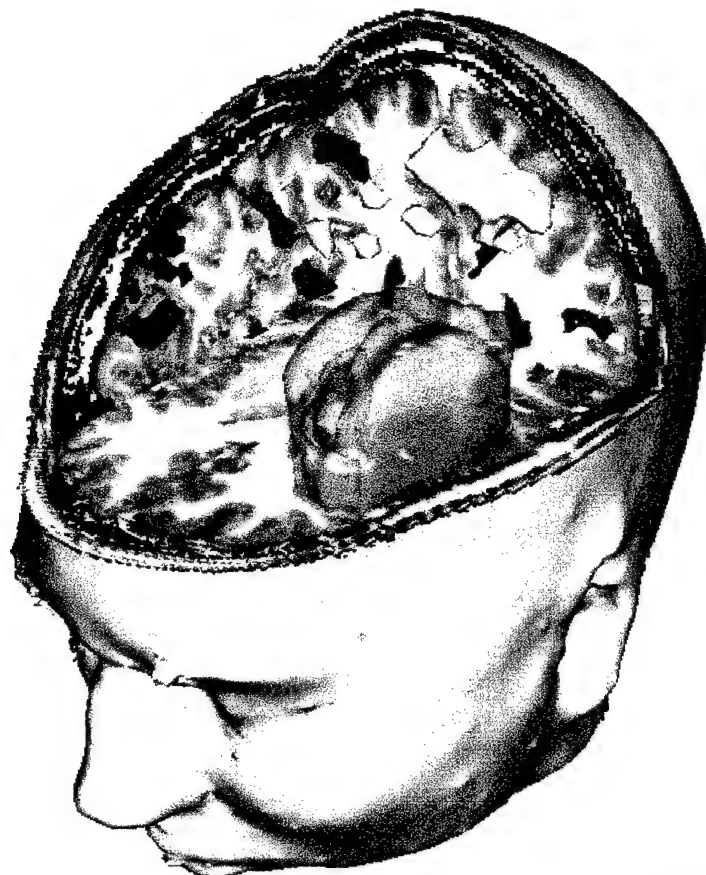
10 Appendices
10.1 Figures
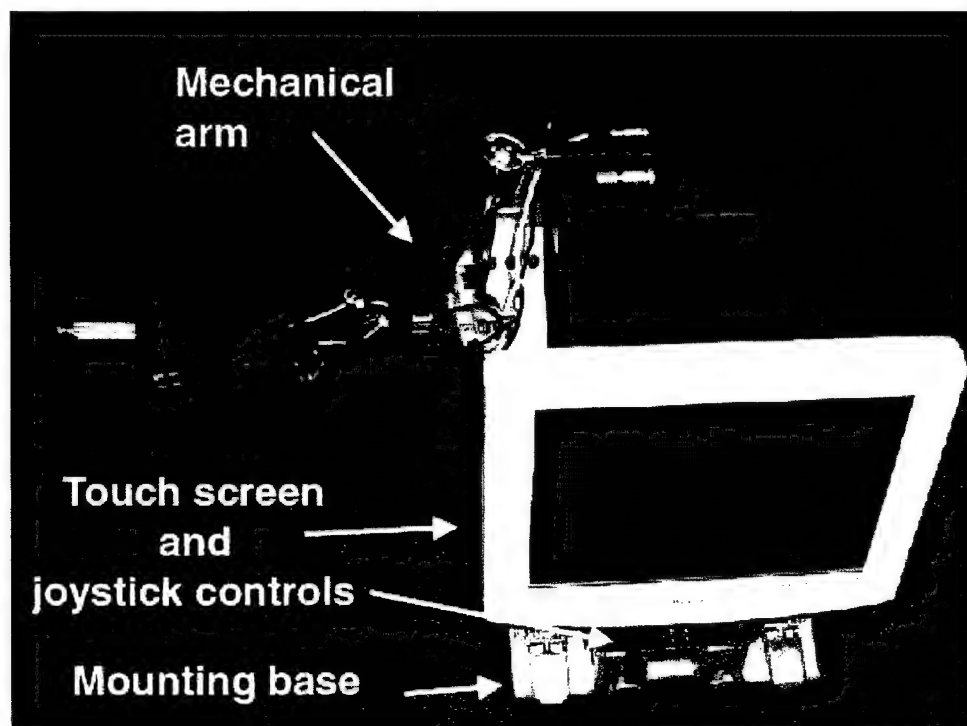
Figure 1: Robotic device showing mechanical arm and joystick control
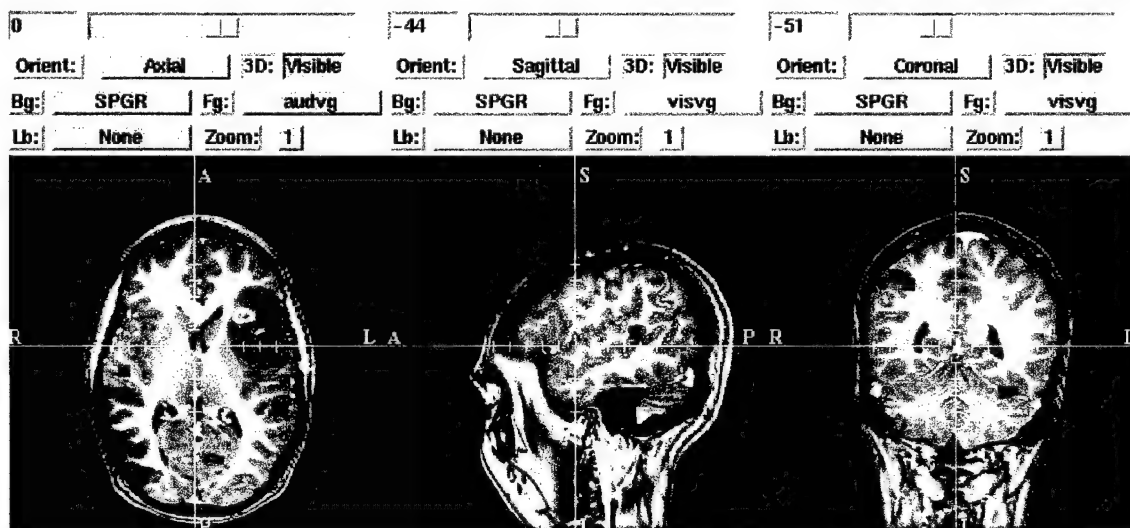(courtesy of Dan Stoianovici, PhD, Johns Hopkins Urology Robotics)

Figure 2: Fluoroscopy servoing sample application showing camera view
of robot and needle and sample robot control panel

Intra-
operative CT

Patient and
Robot
Tracking

Robotic
Assistance

Serial Interface

Robot Control

CT Workstation
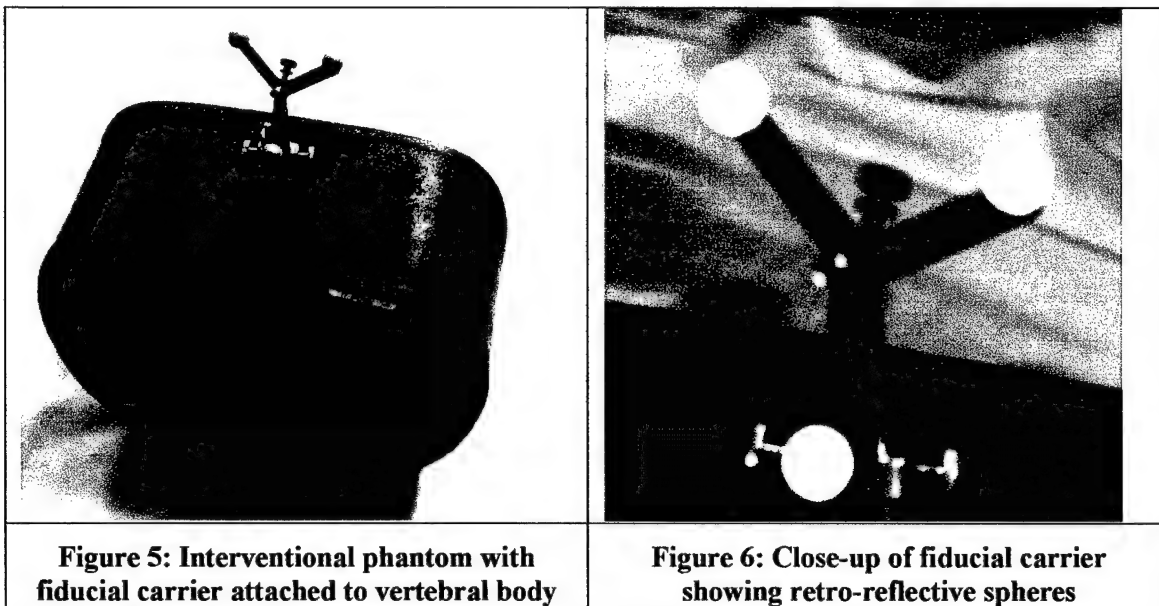
Windows NT Workstation
I-SPINE Software

Ethernet

DICOM

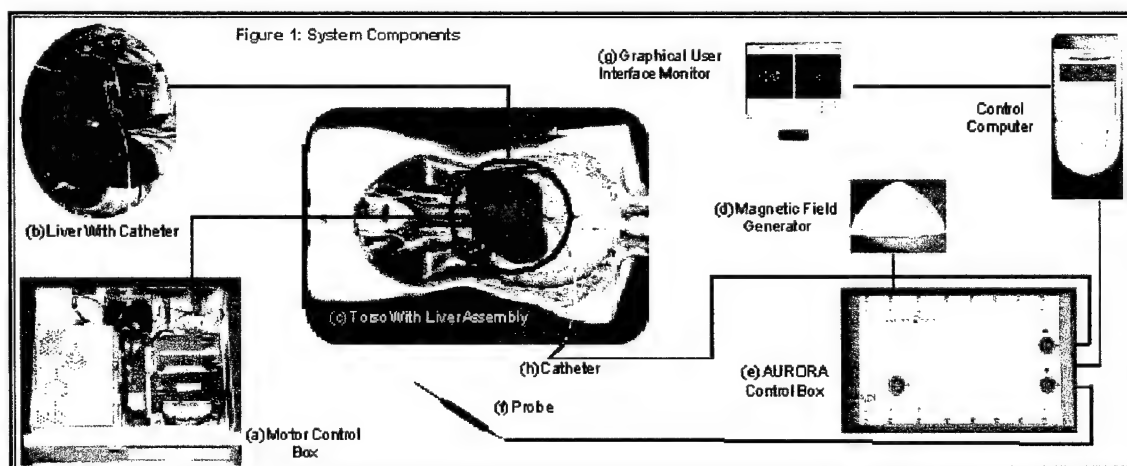**Figure 3: Robot biopsy testbed architecture**

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Figure 4: 3D Slicer User Interface. The 3D Slicer is an open source development project begun at the MIT Artificial Intelligence Laboratory and the Surgical Planning Laboratory at Brigham and Women's Hospital, a teaching affiliate of Harvard Medical School.

Figure 5: Interventional phantom with fiducial carrier attached to vertebral body

Figure 6: Close-up of fiducial carrier showing retro-reflective spheres

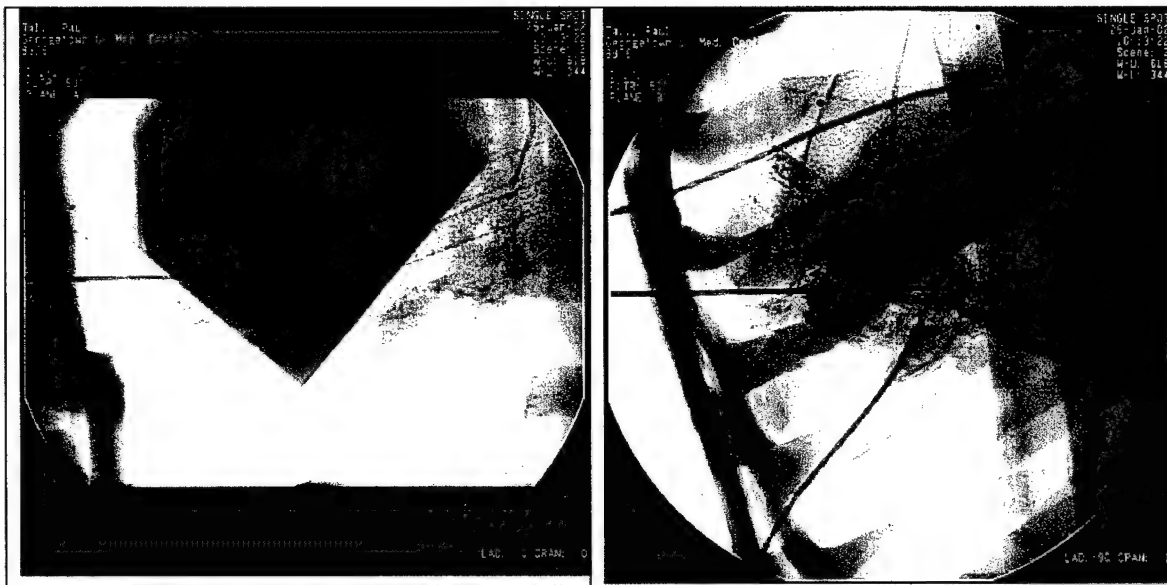X = +280 to +640 mm
Y = –300 to +300 mm
Z = –300 to +300 mm

**Figure 7: AURORA™ sensors, magnetic tracking system components, and measurement volume**

The left picture shows (from left to right) the control unit, sensor interface device, and magnetic field generator. The middle picture shows the sensor coils along with the electrical wires protruding from the coil, compared to a match. The right picture shows the measurement volume in mm relative to the location of the field generator. (Photos courtesy of Northern Digital, Inc.)

Figure 1: System Components

(g) Graphical User Interface Monitor

Control Computer

(b) Liver With Catheter

(d) Magnetic Field Generator

(c) Torso With Liver Assembly

(h) Catheter

(e) AURORA Control Box

(f) Probe

(a) Motor Control Box

Figure 8: Liver respiratory motion simulator and system components

Figure 9: Fluoroscopy images showing needle puncture. Left image is an anterior-posterior view. The needle enters from the left and outline of straws can faintly be seen in middle. Right image is a lateral view. The needle enters from the left and passes through the two straws which form an X. The catheter can also be seen in this figure.
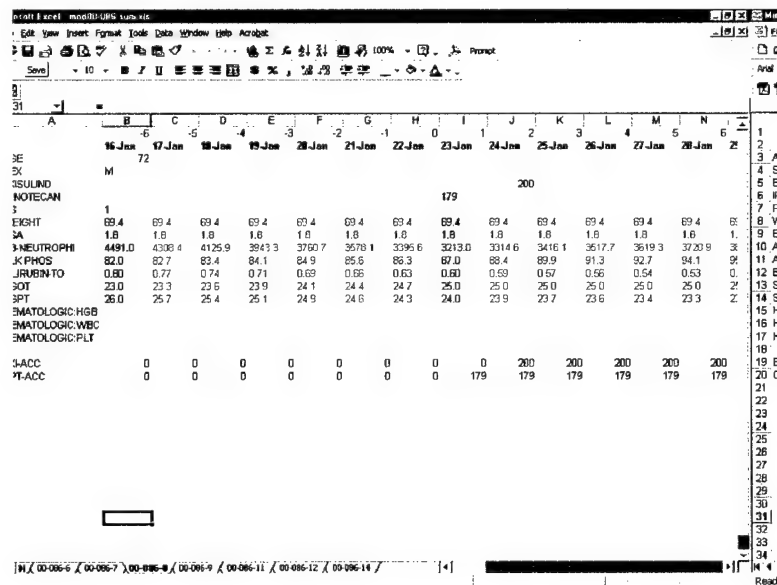
Figure 10: Sample data for chemotherapy dosing study

10.2 Papers

Copies of the two journal papers submitted or published, four conference papers, and one unpublished manuscript are reproduced in this section.

10.2.1   Banovac 2002: Shunt Creation

Reprint begins on the next page and is 20 pages.

Feasibility of percutaneous transabdominal portosystemic shunt creation

F. Banovac, MD[1,2]
E. B. Levy, MD[2]
D. J. Lindisch, RT[1]
A. Pearce, MD[2]
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Running Title: Transabdominal approach for portosystemic shunt creation

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Summary:

Evaluation of the anatomic feasibility of the percutaneous transabdominal puncture of selected portal and hepatic veins in patients with cirrhosis was performed. This approach would become the framework for an image-guided robot-assisted needle drive mechanism for use in Transjugular Intrahepatic Portosystemic Shunt (TIPS) creation. Retrospective analysis of 10 CT and 14 MRI axial abdominal studies was completed to determine whether single simultaneous transabdominal puncture of portal and hepatic veins was possible. A necessary modification of the TIPS procedure was tested in an *ex-vivo* porcine model under fluoroscopy. Eighteen out of 24 patients (75%) had intrahepatic vascular anatomy amenable to a single transabdominal puncture. Successful catheterization of portal and hepatic veins using a modified approach for TIPS was accomplished in two *ex-vivo* porcine livers. A suitable anatomic approach for modified TIPS is present in a majority of patients with cirrhosis. Feasibility of the technique using this anatomic approach was confirmed in two *ex-vivo* porcine models. This study serves as an initial step in a novel technical approach to TIPS using a new anatomic approach for this procedure.

Introduction

The TIPS procedure is performed in a select group of patients with end-stage cirrhosis in order to alleviate their high portal venous pressures and subsequent complications. The most challenging step and the most common source of complications in creation of a transjugular intrahepatic portosystemic shunt (TIPS) is the transparenchymal puncture of the liver to access the portal vein (PV) [3, 13]. The transhepatic puncture begins under fluoroscopic guidance, most commonly in the proximal portion of either the right hepatic vein (RHV) or the middle hepatic vein (MHV), and commences anteriorly and inferiorly toward the portal vein target. A potentially fatal complication during this portion of the TIPS procedure is a puncture of the liver capsule and laceration of the hepatic vessels with subsequent intraperitoneal hemorrhage [4].

A number of investigators have attempted to improve the targeting of the PV in order to minimize the number of passes needed to achieve PV access. Rees et al. [9] described the use of CO_2 wedged hepatic venography to delineate the portal vein. This has been well accepted and is recommended as the current standard for the procedure [1]. Other techniques include transhepatic Doppler ultrasound guidance [6], placement of a platinum-tipped wire in the portal vein to serve as a target during the transhepatic puncture [15], and marking of the PV with microcoils using either ultrasound guidance [10] or CT guidance [2]

Most recently, Rose et al. [11, 12] describe the use of three dimensional ultrasound (3D-US) as an adjunct in accessing the PV. These authors recognized that the PV sometimes moves in the cranial direction relative to the hepatic veins as a consequence of hepatic fibrosis, making the HV-to-PV puncture angle very shallow. This relationship can frustrate transhepatic puncture attempts with the unmodified Colapinto needle.

To more thoroughly investigate the anatomic relationship of the HV and PV in patients with cirrhosis we used multiplanar reconstructions (MPR) of cross sectional CT and MRI images to determine if abdominal imaging could identify an approach for the percutaneous transabdominal simultaneous puncture of a hepatic and portal vein for TIPS creation.

Materials and Methods

Analysis of CT and MRI multiplanar reconstructions

Patients with cirrhosis who underwent abdominal CT or MRI at a single institution between 1994 - 2000 were retrieved from the medical records. Abdominal CT studies (GE HiSpeed Advantage CT) or MRI studies (Siemens Vision 1.5 Tesla) that were available for those patients were retrieved from the storage media and transferred to an independent console using Digital Imaging and Communications in Medicine (DICOM) protocol.

Plug 'n View 3D v.2.3 software (Voxar Limited, Edinburgh, Scotland) was used to construct multiplanar reformatted images (MPR) from the data sets for each patient. All image analysis was performed simultaneously by two authors (F.B., E.L.) For those patients that had more than one CT or MRI study, the earliest available study was used unless the technical quality of the scan precluded the analysis of the hepatic vasculature. Studies were obtained using several abdominal imaging protocols. Studies were excluded if the degree of vascular contrast was inadequate to identify the necessary vessels. Those CT image sets that did not include contiguous sections of the liver could not be reconstructed using the software. CT and MRI axial sections from the level of the diaphragm to the mid-abdomen were used for the MPR.

MR data sets from all available imaging sequences were considered. When multiple sequences were available for a patient, MPR was performed on the sequence that had the most visible signal characteristics of the hepatic vasculature, with or without the concurrent administration of gadolinium. Nevertheless, in some MRI studies the vessels were inadequately visualized and those data sets were not used in our evaluation. A total of 24 out of 36 studies were deemed technically adequate and were analyzed.

First, the RHV and PV were identified on the axial images and an anteroposterior linear cursor was positioned on the RHV within three centimeters of its origin. The oblique MPR containing both the RHV and the RPV was then displayed (Fig.

1a), and the following parameters were measured (Fig. 1a and 1b): distance from the RHV to RPV (Fig. 1a), medio-lateral angle measured between the line connecting the RPV and RHV and the sagital plain (Fig. 1b), and distance from the RHV to the anterior abdominal wall (Fig. 1b).

Insert Figure 1 a,b,c here →

An off-midline sagital MPR containing a proximal portion of the hepatic vein close to the origin with the inferior vena cava and RPV was then obtained. The following parameter was measured; cranio-caudal angle defined by the line connecting the PV and HV and the coronal plane (Fig. 1c). Second, the procedure was repeated for the MHV in relation to RPV and left hepatic vein (LHV) in relation to left portal vein (LPV).

Procedure in an ex-vivo porcine model

Successful simultaneous percutaneous transhepatic puncture of the portal and hepatic veins would require modification of the standard TIPS procedure. Needle puncture of the hepatic and portal veins and successful catheter placement for creation of a portosystemic transparenchymal tract was performed on two *ex-vivo* porcine livers using a catheter pullback technique as described below.

Two livers were harvested from 50 kg pigs which were previously euthanised by another group in a separate investigation. The right and left hepatic and portal veins were filled with a dilute barium suspension. The livers were then placed on a stand in a Siemens Neurostar (Erlangen, Germany) biplane fluoroscopy unit. In

this model the portal vein appeared posterior to the adjacent hepatic vein branch. The needle entry position was then chosen at a site where a portal and hepatic vein branch overlapped in an anterolateral fluoroscopic projection. The needle was then manually driven starting through the more "superficial" hepatic vein and ending in the "deeper" portal vein branch.

An .035 guidewire was passed through the needle and pulled through the portal vein until it exited the portal vein in this excised porcine liver. With the guidewire controlled at both the surface puncture site and at the portal vein, a 5F diagnostic catheter was advanced over the guidewire from the portal vein through the parenchyma and across the hepatic vein. The guidewire was withdrawn, and the catheter was slowly withdrawn (catheter pull back technique) toward the portal vein while constant attempts were made to advance the guidewire from the catheter into the hepatic vein under fluoroscopic guidance. The intraluminal position of the catheter and guidewire within the target hepatic vein was confirmed fluoroscopically. Final images of the wire transversing through the liver parenchyma were obtained. In this anatomic feasibility study the TIPS stent was not deployed and the actual shunt was not created in the ex vivo porcine model.

Results

Analysis of CT and MRI multiplanar reconstructions

A total of 36 patient data sets were transferred to the independent console for analysis. A total of 24 patients had studies that were deemed technically sufficient for retrospective analysis; 10 were MPRs of CT scans and 14 were MPRs of MRI sequences. Eight MRI scans and four CT scans were deemed technically inadequate for analysis. Technical inadequacy was defined as our inability to clearly identify the portal or hepatic veins due to scanning technique, lack of vascular contrast administration, or poor vascular enhancement.

An anatomically feasible percutaneous transhepatic puncture that connects the portal vein with at least one of the hepatic veins was possible in 18 out of 24 patients (75%). None of these 18 patients had any organ interposition that would preclude a successful puncture of the selected veins. Some patients had multiple possible approaches for percutaneous transhepatic TIPS (Table 1).

Table 1 insert here→

The most common feasible approach was the RHV to RPV connection seen in 15 out of 18 successful cases. MHV to RPV approach was possible in 7 of 18 successful cases and LHV to LPV approach was possible in 8 cases.

A total of 30 anatomically feasible approaches for TIPS were possible in our group of 24 patients because some patients had more than one possible approach.

In those patients in which the percutaneous transhepatic approach for TIPS creation was possible, the average measured distance between the respective hepatic veins and portal veins along the path needed for TIPS shunt creation (see Fig. 1a) was 4.83 ± 1.47 cm, n=30. The average distance from the skin through the portal vein and to the hepatic vein (see Fig. 1b) was 16.7 ± 2.9 cm, n=30. Specific distances arranged by the three different vessel relationships that were evaluated are presented (Table 2).

insert table 2 here→

Bowel interposition precluded any kind of percutaneous transhepatic vessel puncture in all six patients with no possible access. Bowel interposition was noted in 6 out of 24 patients for the attempted RPV to RHV connection, and the field of view was inadequate to exclude visceral interposition for the RPV to RHV connection in 2 patients. Additionally, 10 out of 24 patients had bowel interposition for the RPV to MHV approach while 4 patients had bowel interposition and one patient had stomach interposition for the LPV to LHV approach. Overall however, only 6 out of 24 patients had no suitable approach for any of the three proposed approaches.

Demonstration of the procedure in an ex-vivo porcine model

Successful creation of the portosystemic connection was achieved in both *ex-vivo* porcine livers. There were no technical difficulties during the procedure. Representative images of the completed PV to HV connection are shown (Figs. 2 and 3).

Insert figures 2 and 3 here →

Discussion

The TIPS procedure can occasionally be difficult because of the distorted vascular anatomy secondary to hepatic fibrosis. The anatomic variation in hepatic vascular anatomy as it pertains to TIPS has been well documented [5, 14]. Multiple investigators have noted that shrunken livers are often accompanied by a cranially displaced portal vein [12, 14]. Rose et al. reported that 35% of the patients in their series had this anatomic relationship. This can make the angle between the HV and the target PV shallow, making it difficult to accomplish a transhepatic catheterization of the PV without modification of the Colapinto needle and multiple puncture attempts.

Various methods have been suggested to facilitate the TIPS procedure [2, 6, 9-12, 15]. All methods seek to improve the accuracy of the transhepatic puncture of the portal vein. This puncture is the most technically demanding portion of the TIPS procedure. In fact, major complications due to liver perforation with laceration of the hepatic vessels and intraperitoneal hemorrhage have been reported [3, 13] and are a direct result of the inability to target a specific, intrahepatic segment of the portal vein.

We performed multiplanar reconstruction on 36 cross sectional studies in an attempt to determine the anatomic feasibility for a novel approach in shunt

creation for TIPS. Vessel visualization was adequate for analysis of their anatomic relationships in only 24 studies. We attribute this inability to the fact that most of these studies were not optimized for hepatic venous vascular enhancement. Nevertheless, 75% of the patients with cirrhosis had at least one feasible approach between the PV and the HV which would allow for shunt creation.

In our evaluation, the length of the shunt created using this modified TIPS procedure averaged less than 6 cm for any of the three approaches (RHV to RPV, MHV to RPV, and LHV to LPV); this is not substantially different from the shunt lengths used in present clinical practice. Placement of a significant additional number of stents in the percutaneous approach is not anticipated.

Several potential advantages are envisioned in this approach to TIPS. Quinn et. al. [8] already described a similar approach using CT guidance to create a shunt between the PV and the intrahepatic portion of the IVC. They state however that this approach should not be attempted in patients with coagulopathy that cannot be corrected to near normal values. Additionally, the covered stent used in their series partially protrudes into the IVC and can preclude liver transplantation. Shunt creation between the hepatic and portal veins as opposed to portal vein-to-IVC should not preclude the option for transplantation. We propose an initial percutaneous transhepatic puncture using 20 or 22 gauge needles. Utilization of these needles in other percutaneous hepatobiliary procedures such as liver biopsy

is associated with a low, 0.33 - 2.8 % incidence of intraperitoneal hemorrhage [7, 16] and we believe our approach would be associated with a similarly low incidence of intraperitoneal hemorrhage. Further studies are necessary to confirm this potential advantage in clinical practice.

Prospective use of CT imaging can reveal anatomic relationships of vessels allowing for optimal approach selection for this percutaneous anterior technique for TIPS. An unfavorable angular relationship occurs in the cirrhotic liver more frequently than previously believed [12]. Rose et al. also demonstrated that after the interventional radiologist had selected a hepatic vein and rendered an opinion on which hepatic vein was selected based on the appearance at fluoroscopy and digital subtraction angiography, he or she were incorrect 45% of the time [12]. This is important as an anteriorly directed needle pass from the RHV has a reasonable likelihood of PV access, whereas a similarly directed puncture from the MHV has a lower chance of successful PV access and is associated with an increased risk of capsular perforation [11].

Intrahepatic portocaval systemic shunts have been accomplished via transjugular and percutaneous transhepatic approaches. The ability to accurately characterize the anatomic relationship between target hepatic and portal veins using preoperative axial CT images in our study demonstrates the feasibility of an anterior percutaneous transhepatic shunt creation procedure in the majority of

candidates. With additional study, we hope to demonstrate the feasibility of this approach in an animal model. Respiratory motion of the liver will be an additional factor influencing accurate needle placement, and we are investigating the suitability of a magnetic tracking system to monitor the respiratory-related motion of the intrahepatic vessels. It is conceivable that complications and morbidity of TIPS may be further reduced in the future by the employment of accurate image-guided robotic needle placement assistants and preoperative plans derived from similar axial CT analysis. Needle guidance assist devices which can compensate for respiratory motion are currently under development, although none are commercially available for routine clinical use. Combining preoperative image-based planning with needle guidance assist devices may enhance the safety of the TIPS procedure by reducing the number of puncture attempts required to achieve successful shunt placement. This will however have to be confirmed in clinical studies.

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Table 1: Analysis of possible approaches for percutaneous transhepatic single puncture connection between the hepatic and portal venous systems in 24 patients.

At least one possible approach	18 (75%)
Only one possible approach	9 (38%)
Two possible approaches	6 (25%)
Three possible approaches	3 (13%)
No approach possible	6 (25%)

Table 2: Distances and angles for anatomically feasible percutaneous approaches to TIPS

Veins involved	Shunt average mean distance ± SD (range)	Hepatic vein to skin mean distance ± SD (range)	Cranio-Caudal mean angle ± SD (range)	Medio-Lateral mean angle ± SD (range)
RPV to RHV (n=15)	5.4 ± 1.5 cm (3.4 – 9.0)	16.9 ± 3.5 cm (12.6 – 23.7)	42.0 ± 11.3° (19° – 73°)	29.3 ± 18.0° (18 – 62°)
MHV to RPV (n=7)	3.8 ± 1.2 cm (1.6 – 5.4)	16.0 ± 2.8 cm (11.0 – 18.7)	41.2 ± 12.4 (24° - 59°)	25.3 ± 23.5° (-6° – 60°)
LHV to LPV (n=8)	4.7 ± 1.1 cm (3.3 – 6.4)	16.9 ± 1.9 cm (13.6° – 19.0°)	41.0 ± 15.45° (18° - 65°)	24.4 ± 22.5° (-24° - 48°)
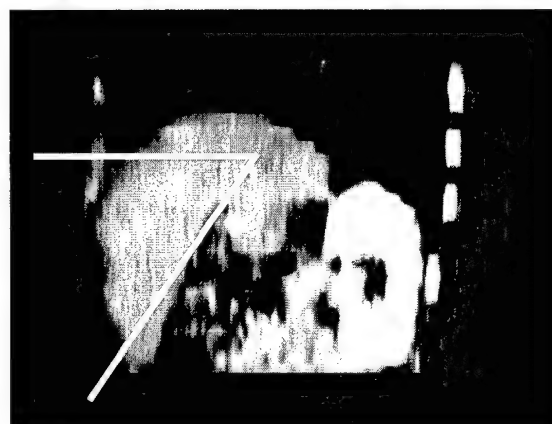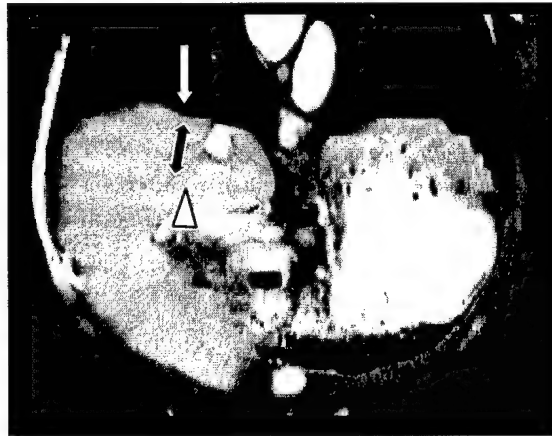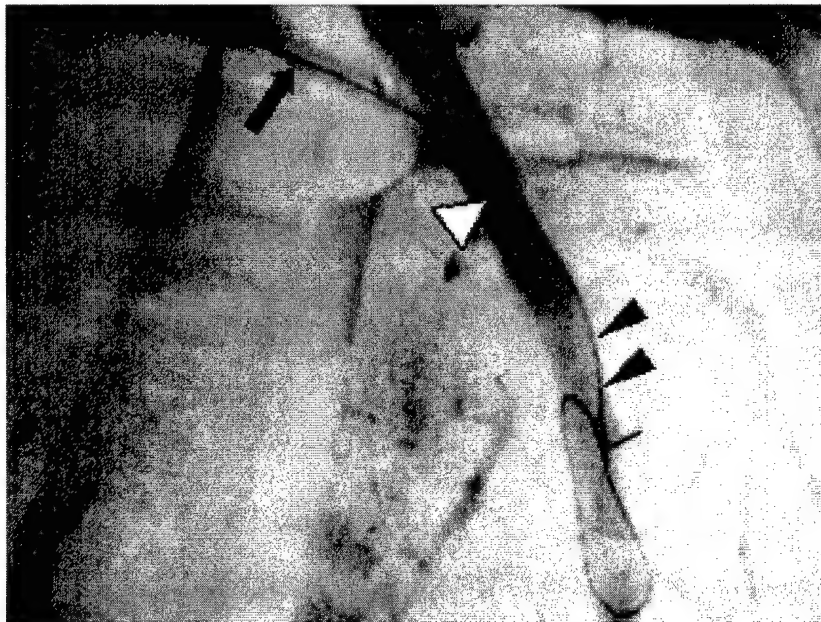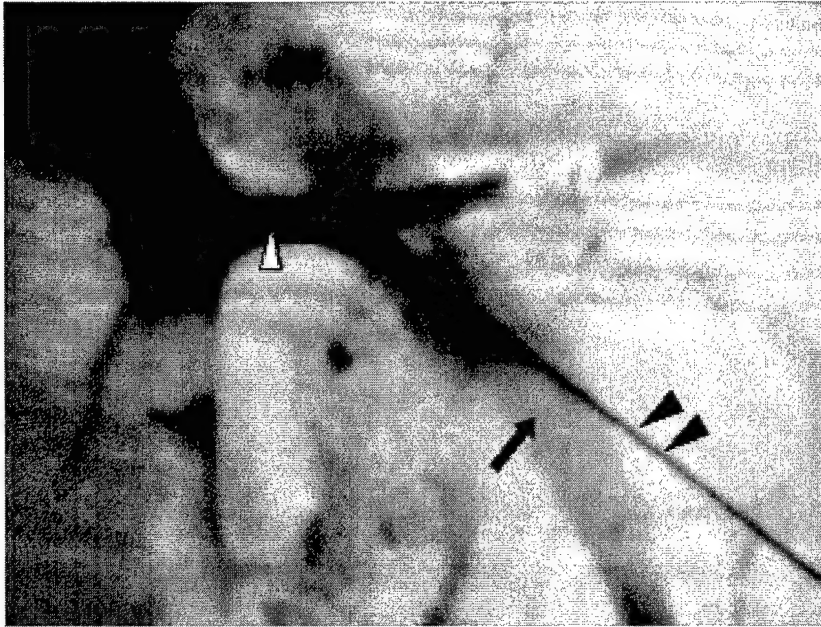
Figure Legends

Figure 1

(A) Oblique MPR from a CT dataset in the plane that demonstrates the right hepatic vein (white arrow) and the right portal vein (white arrowhead). The double headed black arrow represents the distance measurement corresponding to the proposed TIPS;

(B) Oblique MPR from labeled with the mediolateral angle (black lines) as measured between the line parallel to the proposed TIPS and the sagital plane. Skin-to-RHV distance for transhepatic vascular puncture is shown by the double headed white arrow;

(C) Representative sagital MPR from a CT dataset demonstrating the cranio-caudal angle (white lines) defined by a line parallel to the proposed TIPS and the axial plane.

Figure 2

Digital image of the ex-vivo porcine liver showing simultaneous single needle puncture of a hepatic and portal vein from a "percutaneous" transhepatic approach. The targeted portal vein branch (white arrowhead); black arrow denotes the targeted hepatic vein, and (black arrowheads) show the needle and a guidewire in position.

Figure 3

A 5F catheter has been advanced over the guidewire from the accessed portal vein and into the hepatic vein. The catheter is then withdrawn through the hepatic parenchyma toward the portal vein (black arrow) until the tip enters the hepatic vein lumen (white arrowhead) and the guidewire (black arrowheads) can be advanced into the hepatic vein.

10.2.2   Cleary 2002: Liver Motion Simulator

Reprint begins on the next page and is 5 pages.

Development of a Liver Respiratory Motion Simulator to Investigate Magnetic Tracking for Abdominal Interventions

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Georgetown University, Washington, DC

ABSTRACT

We have designed and constructed a liver respiratory motion simulator as a first step in demonstrating the feasibility of using a new magnetic tracking system to follow the movement of internal organs. The simulator consists of a dummy torso, a synthetic liver, a linear motion platform, a graphical user interface for image overlay, and a magnetic tracking system along with magnetically tracked instruments.

While optical tracking systems are commonly used in commercial image-guided surgery systems for the brain and spine, they are limited to procedures in which a line of sight can be maintained between the tracking system and the instruments which are being tracked. Magnetic tracking systems have been proposed for image-guided surgery applications, but most currently available magnetically tracked sensors are too small to be embedded in the body. The magnetic tracking system employed here, the AURORA™ from Northern Digital, can use sensors as small as 0.9 mm in diameter by 8 mm in length. This makes it possible to embed these sensors in catheters and thin needles. The catheters can then be wedged in a vein in an internal organ of interest so that tracking the position of the catheter gives a good estimate of the position of the internal organ. Alternatively, a needle with an embedded sensor could be placed near the area of interest.

To demonstrate this concept, our liver respiratory motion simulator includes a synthetic liver mounted on a one degree of freedom linear motion platform. The linear motion platform is computer controlled, allowing arbitrary respiratory motion cycles to be simulated. The liver includes veins so that a catheter can be placed inside it. A graphical user interface (GUI) has been developed based on the VTK (Visualization Toolkit) graphics package. The GUI allows the user to view a set of axial CT slices of the liver and track the moving liver in real-time, as well as display an image overlay of a magnetically tracked probe. This type of GUI could be used in future studies such as biopsy of internal organs while compensating for respiratory motion.

This paper describes the simulator components and presents our concept for using magnetic tracking to assist the physician in targeting internal organs, including the tracking of respiratory motion. We believe this will be a first step in extending image-guided surgery from the current stage of tracking of rigid objects such as the skull and vertebral bodies to the tracking of internal organs and compensation for respiration.

Keywords: simulator, respiratory motion, liver, magnetic tracking, computer-assisted surgery, image-guided surgery

1. INTRODUCTION

A number of commercially available surgical navigation systems exist. However, these systems are targeted at cranial, orthopedic, and maxillofacial procedures since bony landmarks are available. Internal organs such as the liver present problems since they may be subject to considerable respiratory motion. The recent availability of small magnetically tracked sensors may enable surgical navigation to be extended to organs that move with respiration. To evaluate this new tracking technology, our research group has developed a liver respiratory motion simulator as described in this paper. While many groups have created surgical simulators (see for example, recent proceedings of this conference or the *Medicine Meets Virtual Reality* meeting), to our knowledge this is the first liver simulator specifically designed to incorporate respiratory motion.

[*] cleary@georgetown.edu; phone 1 202 687-8253; fax 1 202 784-3479; http://www.visualization.georgetown.edu; Imaging Science and Information Systems (ISIS) Center, Department of Radiology, Georgetown University Medical Center, 2115 Wisconsin Avenue, Suite 603, Washington, DC, USA 20007. **Georgetown University Hospital.

2. SYSTEM COMPONENTS

The components of the system are shown in Figure 1. The system consists of:

1) torso with liver assembly and linear motion platform
2) silicon liver
3) motor control box
4) graphical user interface
5) control computer
6) magnetic field generator
7) AURORA control unit
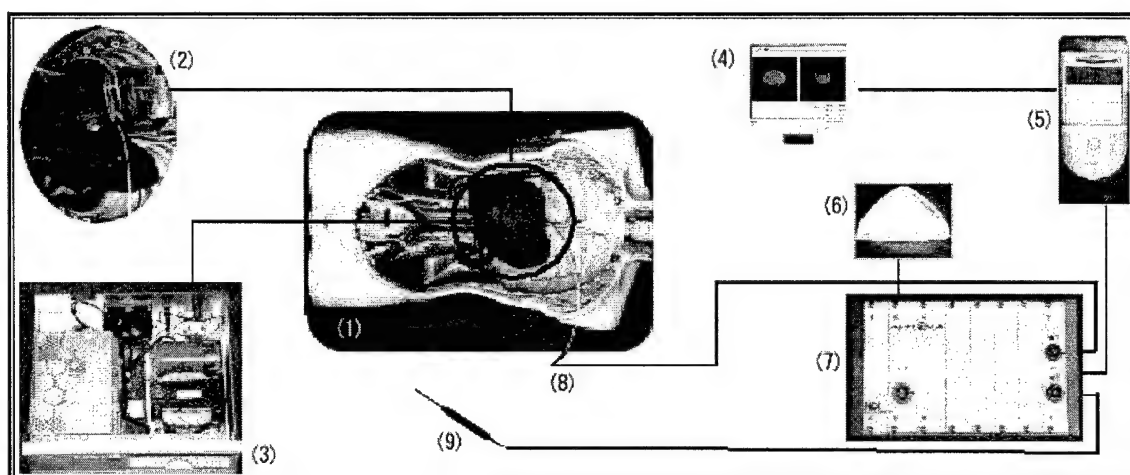8) magnetically tracked catheter
9) magnetically tracked probe

Figure 1: Liver respiratory motion simulator components

These components will be described in the following sections. The clinical scenario for using this system to demonstrate percutaneous abdominal interventions is as follows:

1. A magnetically tracked catheter is wedged in the hepatic vein of the liver
2. Several skin fiducials are placed surrounding the liver
3. The simulator is placed in the CT scanner
4. A series of thin 1-2 mm axial slices are obtained from the base of the lungs through the liver while the liver is kept in end-expiration (simulating the breath-hold technique used in clinical practice)
5. The catheter is left in place and the simulator is moved to the interventional table
6. The magnetic field generator is placed near the liver
    i. The position of the catheter is read in magnetic space
    ii. The position of the skin fiducials is read in magnetic space by touching each fiducial with the probe
7. The position of the catheter and fiducials is determined in CT space by asking the interventional radiologist to select these points on the CT images
8. A registration algorithm is invoked to determine the transformation matrix from magnetic space to CT space
9. The interventionalist uses the magnetic probe to approach the liver as he/she would during percutaneous liver biopsy or tumor ablation
10. The probe is tracked in real-time and the transformation matrix computed in step 9 is used to compute the overlay of the probe on the CT images
11. The monitor displays cross sectional CT images of the liver reformatted in a plane parallel to the magnetic probe. This allows the interventionalist to view the projected path of the instrument in real-time.
12. The cross sectional image can be displayed either with the motion platform stopped (simulating a breath hold) or while the liver is moving (simulating a respiring patient). If the liver is moving, the magnetically tracked catheter is used to update the current position of the liver.

2.1 Hardware: Torso, Liver Assembly, and Linear Motion Platform

The major hardware components of the simulator are the torso, liver, and linear motion platform. A commercially available torso model (Tall Paul torso, Tri-Ess Sciences Inc., Burbank, CA, USA) was used as the starting point (Figure 2). This torso includes 19 removable organs, but these organs were not used except for the liver as described below. The torso was mounted on a wooden platform along with the linear motion platform.

Using the removable liver from the torso as a mold, a silicon liver phantom was constructed (Figure 3). This phantom incorporated several important physical and imaging characteristics. Made from cured silicone rubber VI-SIL 1068 (Rhoda VSI, Troy, NY, USA) and cast into a custom made Instamold (Active Products, Marshall, TX, USA), the liver contains tubular, branching vein models (vena cava and hepatic veins). It also incorporates radio-opaque nodular 1-2 cm tumors. The tumors were made by adding dilute hypaque radiographic contrast medium to the silicone compound prior to curing.
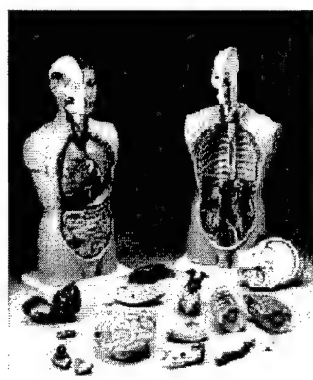

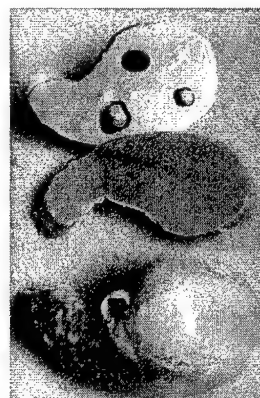Figure 2: Torso model and removable organs

Figure 3: Silicon liver model

To provide liver motion, a linear motion platform was incorporated into the simulator. The linear motion platform consisted of a passive linear slide and a driven linear slide (American Linear Manufacturers, Westbury, NY, USA) as shown in Figure 4. The driven slide is connected to a digitally controlled servomotor (Bearing Engineers, Burlingame, CA, USA). The slides were mounted on a wooden base and a piece of plexiglass was attached to the top of the slides. This was done so the space between the slides would be radiolucent to allow for x-ray imaging of the liver. The liver model is then mounted on the plexiglass using plastic bolts and nuts.
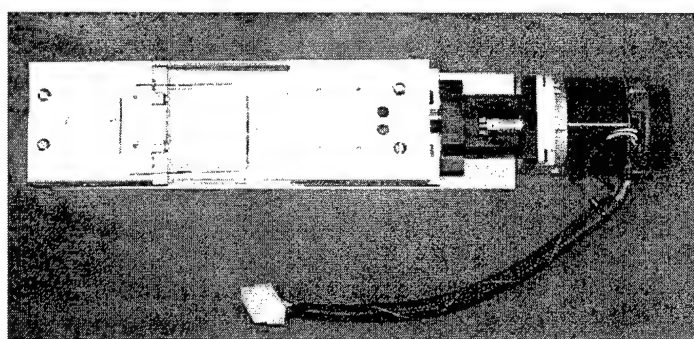

Figure 4: Linear motion platform

2.2 AURORA Magnetic Tracking System

Recently, a new magnetic tracking system (AURORA[TM]) based on miniature sensor coils has been developed by Northern Digital (Waterloo, Ontario, Canada). The system consists of a control unit, sensor interface device, and field generator as shown in the left hand picture in Figure 5. The sensors (middle photo) plug into the sensor interface unit and can be as small as 0.9 mm in diameter and 8 mm in length. The sensor coil is shown next to a match with the leads

protruding from the coil. This extremely small size makes it possible to embed these sensors into surgical instruments. According to the manufacturer's specifications, the sensors have a positional accuracy of 1-2 mm and angular accuracy of 0.5-1 degree. The measurement volume is also illustrated in Figure 5 (right hand photo) based on the reference coordinate system of the field generator. The distance along the x-axis is 280 to 640 mm, along the y-axis from –300 to 300 mm, and along the z-axis from –300 to 300 mm. This volume is sufficient to cover the area of interest for liver RF ablation. This technology was originally developed by European researchers for real-time position sensing of tumors, catheters, and flexible endoscopes[1,2].
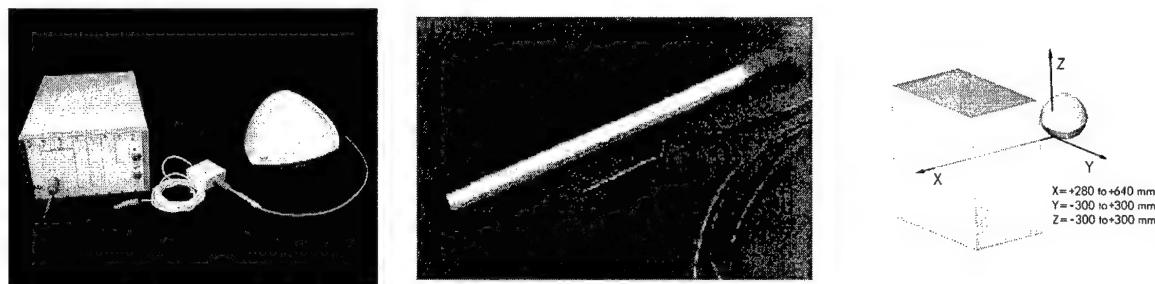

Figure 5: AURORA sensors, magnetic tracking system components,
and measurement volume (courtesy of Northern Digital, Inc)

The picture on the left shows (from left to right) the control unit, sensor interface device, and magnetic field generator. The middle picture shows the sensor coils along with the electrical wires protruding from the coil, compared to a match. The picture on the right shows the measurement volume in mm relative to the location of the field generator.

The manufacturer's specifications for the AURORA are shown in Table 1.

	5D Sensor	6D Sensor
Accuracy positional	1 - 2 mm 3D RMS[1]	1 mm 3D RMS
Accuracy angular	0.5° - 1° RMS[1]	0.5° RMS
Sensor		
Dimensions	0.9 mm dia. x 8 mm	Customized
Number of Sensors	1 - 10	1 - 10
Measurement Rates	20 - 60 Hz[2]	20 - 60 Hz[2]
Sensor Interface Unit		
Dimensions	60 mm x 60 mm x 25 mm	
Weight	75 g	
Field Generator		
Dimensions	225 mm x 225 mm x 210 mm	
Weight	2 kg	
System Control Unit		
Dimensions	365 mm x 235 mm x 135 mm	
Weight	5 kg	

[1] accuracy varies with sensor orientation
[2] independent of number of sensors tracked

Table 1 (Courtesy of Northern Digital, Inc.)

2.3 Software and User Interface

A graphical user interface was developed to display pre-procedure CT scans along with an overlay of the probe on the liver (Figure 6). The software can display axial, sagittal, and coronal reconstructions along with oblique slices relative to the position and orientation of the magnetic instrument probe. The software was developed under Windows NT using Visual C++. The Visualization Toolkit (VTK) was used along with the Fast Light Toolkit (FLTK) for the user interface

elements. The user interface and system were demonstrated at the Computer Aided Radiology and Surgery (CARS) meeting in Berlin in June 2001. Since that demonstration, recent work has focused on improvements to the user interface and the addition of targeting assistance for the physician.

3. PRELIMINARY RESULTS: CADAVER STUDY

Preliminary experiments using the liver respiratory motion simulator showed reasonable accuracy, so it was decided to test the system in the interventional suite using a cadaver. The goal of this test was to see if the system could be used to precisely place a needle into a pre-determined location in the liver. As a target point, a small (1 mm in diameter) metal BB was placed in the liver several cm below the skin (Figure 7). For registration purposes, several BBs were also placed on the skin. These BBs and a magnetically tracked catheter placed in the liver were used to register the CT images with the magnetic tracker. A magnetically tracked needle was then used to try and target the BB in the liver. All the magnetically tracked instruments worked fine, but problems with correctly transferring the DICOM files and reading the DICOM header information prevented us from obtaining an accurate registration. The software has since been fixed and further studies are planned.
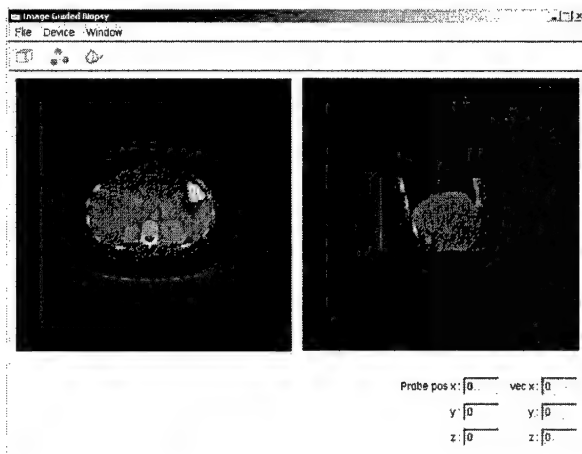

Figure 6: Graphical user interface (axial and sagittal views shown)

Figure 7: Cadaver study – inserting target BB into the liver

4. SUMMARY

A liver respiratory motion simulator has been designed and constructed as a first step in demonstrating the feasibility of using a new magnetic tracking system to follow the movement of internal organs. To our knowledge this is the first liver simulator which incorporates respiratory motion. We believe this will be a first step in extending image-guided surgery from the current stage of tracking rigid, bony anatomical landmarks to the tracking of internal organs and compensation for respiration. The work described in this paper is an initial start, but much work remains to be done. To this end, we plan to carry out a series of phantom and animal experiments.

ACKNOWLEDGEMENTS

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10.2.3   Cleary 2001a: Surgical Robotics Review

Reprint begins on the next page and is 26 pages.

Title Page

State of the Art in Surgical Robotics:
Clinical Applications and Technology Challenges

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Abstract

While it has been over 15 years since the first recorded use of a robot for a surgical procedure, the field of medical robotics is still an emerging one that has not yet reached a critical mass. While robots have the potential to improve the precision and capabilities of physicians, the number of robots in clinical use is still very small. In this review article, we begin with a short historical review of medical robotics, followed by an overview of clinical applications where robots have been applied. The clinical applications are then discussed, which include neurosurgery, orthopedics, urology, maxillofacial surgery, radiosurgery, opthamology, and cardiac surgery. We conclude with a listing of technology challenges and research areas, including system architecture, software design, mechanical design, imaging compatible systems, user interface, and safety issues.

Key Words

Medical robotics, review article, technology challenges, neurosurgery, orthopedics, urology, maxillofacial surgery, radiosurgery, opthamology, and cardiac surgery

1.0 Introduction

Medical robotics has tremendous potential for improving the precision and capabilities of physicians to perform surgical procedures. However, we are just at the beginning of the application of robotics to medicine, and many questions remain open regarding effectiveness, safety, and cost. While there are several commercial companies selling medical robots, the total installed number is extremely small, and the market will most likely continue to grow slowly. Unlike the area of factory robotics, which grew rapidly during the 1970s and 1980s, medical robotics has not yet reached a critical mass. However, it is believed the benefits of medical robotics will become increasingly clear and this will lead to a continued rise in their use in medicine.

According to the Robotic Institute of America, a robot is *"a reprogrammable, multifunctional manipulator designed to move materials, parts, tools, or other specialized devices through various programmed motions for the performance of a variety of tasks."* While the term "robot" may conjure up images of R2D2 from the movie "Star Wars", in this paper we will stay with the definition above. These robots consist of nearly rigid links that are connected with joints that allow relative motion from one link to another [1]. Attached to the end of the links is the robot hand, usually referred to as the end-effector. The robot is controlled by a computer system that is used to move the end-effector to any desired point and orientation within its workspace.

This review article highlights the state of the art of medical robotics across several clinical areas. In this review, we will focus on robots that play an active role during a surgical intervention. These systems are not meant to replace the physician, but rather to augment the capabilities of the physician. There are other categories of medical robotics, such as robotics for rehabilitation or miniature robots that might be placed inside the body, but these will not be discussed here. This review is not intended to be comprehensive, but rather to give an overview of the field, with a focus on key historical developments and on current work.

Several other medical robotics review articles with a focus on surgical procedures have also been written. Davies [2] describes the history of surgical robotics and gives one classification for the types of robot systems studied by researchers. Taylor [3] discusses several taxonomies for surgical robotics and presents a different classification. Troccaz [4] gives a historical review and describes passive, semi-active, and active robotic systems. Howe [5] overviews applications in image-based procedures, orthopedic surgery, and neurosurgery, among others. Specialized reviews also exist, such as the article by Caddedu on urology robotics [6].

The paper is organized as follows. Section 2 gives a brief historical review, followed by a table of clinical applications in Section 3. Each of these clinical applications is then described. Section 4 presents technology challenges and research areas. Conclusions are given in Section 5.

2.0 Historical Review

Medical robotics is a relatively young field, with the first recorded medical application of a robot occurring in 1985 [7]. In this case, the robot was a simple positioning device to orient a needle for biopsy of the brain. A 52-year-old man was put on a CT scanner table, the target was identified on the CT images, and the robot was used to orient a guide tube through which a needle was inserted. Unfortunately, the robot used was a PUMA 560 industrial robot, and safety issues concerning the operation of the robot in close proximity to people prevented this work from continuing [2].

Shortly thereafter, research groups in Europe, Asia, and the United States began investigating medical applications of robotics. In Europe, a group at Imperial College in London under the direction of Davies began developing a robot for prostate applications [8]. At Grenoble University Hospital in France, Benabid, Lavallee, and colleagues started work on neurosurgical applications such as biopsy [9]. In Asia, Dohi at Tokyo University developed a prototype of a CT-guided needle insertion manipulator [10]. In the U.S., Taylor and associates at IBM began developing the system later known as ROBODOC [11].

Currently, there are several commercial ventures and a handful of research laboratories active in the field of medical robotics. These early research efforts have led to some commercial products. For example, the work at Grenoble University Hospital led to the NeuroMate robot of Integrated Surgical Systems as described in Section 3.1.2.

3.0 Clinical Applications

There are several ways to classify the use of robots in medicine. One scheme, as developed by Taylor [3], is to classify robots by the role they play in medical applications. Taylor stresses the role of robots as tools that can work cooperatively with physicians to carry out surgical interventions and identifies five classes of systems:
1. Intern replacements
2. Telesurgical systems
3. Navigational aids
4. Precise positioning systems

5. Precise path systems

While this classification is technology oriented, we have chosen to divide the field by clinical application in this paper. Clinical applications are more interesting to the end-user, and a list of seven clinical areas where robotics have been applied is shown in Table 1. This table is not meant to be inclusive, but representative research groups and commercial vendors in several areas have been selected to give the reader an overview of the field. The column labeled "Studies" refers to whether human trials, animal studies, cadaver studies, or other studies have been done.

Table 1. Clinical Application Areas and Representative Robotic Developments

| Clinical Area	Country	Institution / Company	System	Studies	Reference
Neurosurgery	Switzerland	Univ. of Lausanne	Minerva	Human	[12, 13]
Neurosurgery	USA	Integrated Surgical / Grenoble Univ. Hospital	NeuroMate	Human	[14]
Neurosurgery	Japan	Univ. of Tokyo	MRI compatible	Tissue samples	[15]
Orthopedic	USA	Integrated Surgical	ROBODOC	Human	[11]
Orthopedic	USA	Georgetown/Hopkins	PAKY/RCM	Cadaver	[16, 17]
Orthopedic	USA	Univ of Tokyo/Hopkins	PAKY/RCM	Phantom	This issue
Orthopedic	USA	Marconi	Kawasaki	Pig	This issue
Orthopedic	UK	Imperial College	Acrobot	Human	This issue
Urology	UK	Imperial College	Probot	Human	[18]
Urology	USA	Hopkins	PAKY/RCM	Human	This issue
Maxillofacial	Germany	Charite	SurgiScope	Pig	[19]
Maxillofacial	Germany	Karlsruhe/Heidelberg	RX 90	Pig	[20]
Radiosurgery	USA	Accuray	CyberKnife	Human	[21]
Opthamology	USA	Hopkins	Steady-Hand	In development	[22]
Cardiac	USA	Intuitive Surgical	da Vinci	Human	[23]
Cardiac	USA	Computer Motion	Zeus	Human	[24]
Cardiac	France	Grenoble	PADyC	In development	This issue

3.1 Neurosurgery

As mentioned in the historical review, neurosurgery was the first clinical application of robotics and continues to be a topic of current interest. Neurosurgical stereotactic applications require spatial accuracy and precision targeting to reach the anatomy of interest while minimizing collateral damage. This section presents three neurosurgical robotic systems.

1. Minerva from the University of Lausanne in Switzerland
2. NeuroMate from Integrated Surgical Systems in the U.S.
3. An MRI compatible robot developed by Dohi and colleagues in Japan

3.1.1 Minerva

One of the earliest robotic systems developed for precise needle placement was the neurosurgical robot Minerva [13], designed for stereotactic brain biopsy. A special purpose robot was constructed which was designed to work within the CT scanner so that the surgeon could follow the position of the instruments on successive CT scans. This constraint ensured that CT images would be available throughout a procedure, keeping all procedures under the surgeon's supervision and control. A diagram of the system and associated components is shown in Figure 1.

The mechanical design of this system was presented in [12]. The system consists of a five degree of freedom structure with two linear axes (vertical and lateral), two rotary axes (moving in a horizontal and vertical plane), and a linear axis (to move the tool to and from the patient's head). The robot is mounted on a horizontal carrier, which moves on rails. A stereotactic frame, the Brown-Roberts-Wells (BRW) reference frame, is attached to the robot gantry and coupled to the motorized CT table by two ball and socket joints arranged in series. The system was used for two operations on patients in September 1993 at the CHUV Hospital in Switzerland, but the project has since been discontinued.
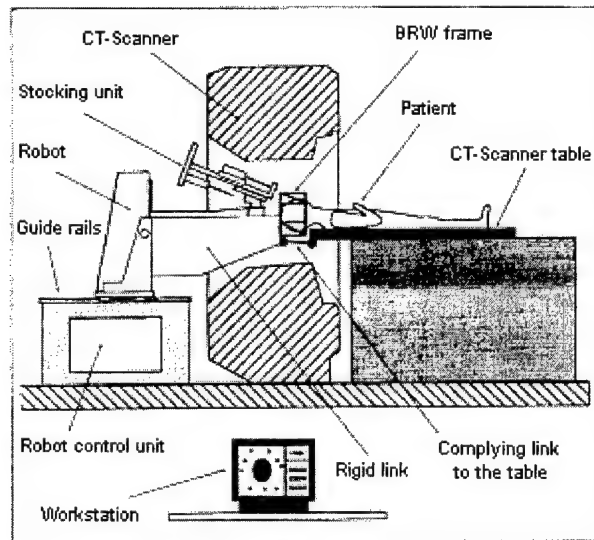

Figure 1: Minerva components and system overview
(© 1995 IEEE, from [13])

3.1.2 NeuroMate

The NeuroMate is a six-axis robot for neurosurgical applications that evolved from work done by Benabid, Lavallee, and colleagues at Grenoble University Hospital in France [9, 14, 25]. The original system was subsequently redesigned to fulfill specific stereotactic requirements and particular attention was paid to safety issues [26]. The current version (Figure 2) is a commercial product that has been licensed by Integrated Surgical Systems (Davis, California, USA) and is FDA approved.
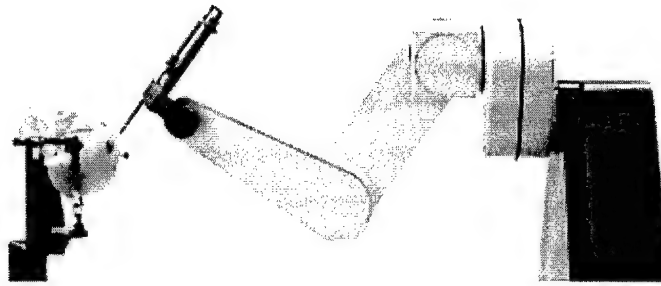
Figure 2. NeuroMate neurosurgical robot
(courtesy of Integrated Surgical Systems, USA)

The system has been used in over 1600 procedures since 1989, covering a range of neurosurgical procedures. The major clinical applications include:

- Tumor biopsies (1100 cases)
- Stereoelectroencephalographic investigations of patients with epilepsy (200 cases)
- Midline stereotactic neurosurgery and functional neurosurgery of the basal ganglia (200 cases)

A typical clinical procedure consists of an initial data acquisition step, followed by data transfer to the control computer, and then the procedure itself. Data acquisition involves obtaining images of the brain from which path planning from the skin entry point to the target point can be done using a specially developed software program. The images can be in digital form (DSA, CT, or MRI images) or can be digitized (radiographs, for example) using a digitizing table or scanner. Once the path is planned, the images are transferred directly from the planning workstation to the control workstation in the operating room over an Ethernet link.

To carry out the procedure, the robot must know where it is located relative to the patient's anatomy. This is typically done using a calibration cage, which is placed on the end-effector of the robot around the patient's head (Figure 3). This cage looks like an open cubic box and the four sides are each implanted with nine X-ray opaque beads, the positions of which have been precisely measured. Two X-rays are taken which show the position of these beads along with the fiducial markers of the patient's frame. This information is used to determine the transformation matrix between the robot and the patient. The defined trajectory is used to command the robot to position a mechanical guide, which is aligned with this trajectory. The robot is then fixed in this position and the physician uses this guide to introduce the surgical tool such as a drill, probe, or electrode.
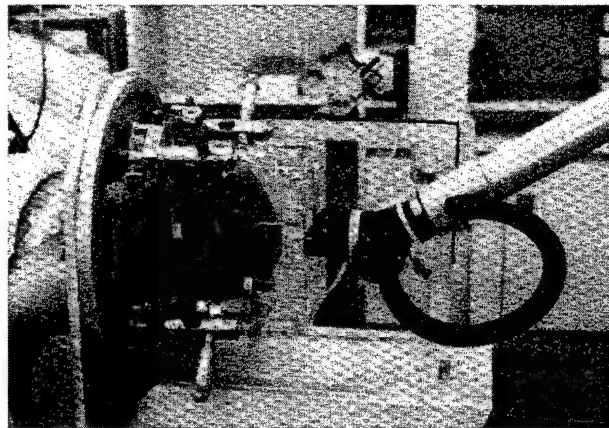
Figure 3: Calibration cage held by the robot
(from [14], used by permission of MIT Press)

3.1.3 <u>MRI compatible robot</u>

While several robots have been developed for stereotactic neurosurgery, including those mentioned above, almost all of these systems used CT images for guidance. However, many structures in the brain are best visualized using magnetic resonance imaging (MRI). The robotic systems described so far are not suitable for use in an MRI scanner because the strong magnetic fields generated dictate that only nonmagnetic materials can be used. In Japan, in the Mechatronics Laboratory at the University of Tokyo, Dohi, Masamune and colleagues developed an MRI-compatible needle insertion manipulator intended for use in stereotactic neurosurgery [15]. The manipulator frame was manufactured using polyethylene terephthalate (PET) and ultrasonic motors was used for the actuators. Other parts such as bearings, feed screws, and gear that must be strong and precisely fabricated are made of non-magnetic materials including brass, aluminum, delrin, and ceramics. In phantom tests using watermelons, the robot performed satisfactorily with a positioning error of less than 3.3 mm from the desired target. The unit was small enough at 491 mm in maximum height to fit inside the MRI gantry of 600 mm in diameter.

Rather than retrofitting an industrial robot, Masamune developed a completely new design based on the clinical requirements for safety, MRI compatibility, and compactness. As shown in Figure 4, the system includes an X-Y-Z base stage. An arch mechanism is mounted on the base stage along with a linear needle carriage. This isocentric design was adopted for its mechanical safety and simplicity. The system was controlled by a personal computer. The control computer and motor driver boards were remotely located in the MRI control room and connected by shielded cables to the robot.
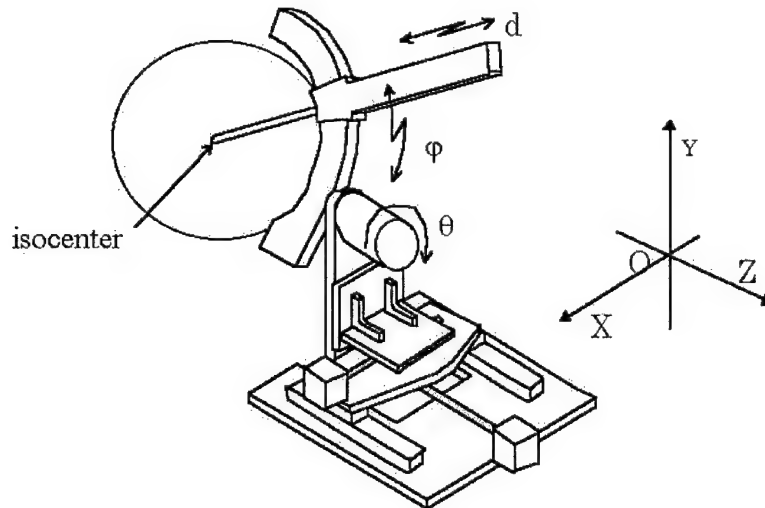
Figure 4: MRI compatible robot design
(courtesy of Ken Masamune, Tokyo Denki University, Japan)

In a related development, a new MRI compatible robot has been developed to work within the interventional MRI unit at the Brigham and Women's Hospital in Boston, Massachusetts, USA [27]. The interventional MRI has a pair of parallel facing donut-shaped magnets, with an air gap of 560 mm. The robot sits between the magnets and is mounted on at the top of the unit as shown in Figure 5. The system is currently undergoing testing, and one potential clinical application is needle placement for prostate brachytherapy.
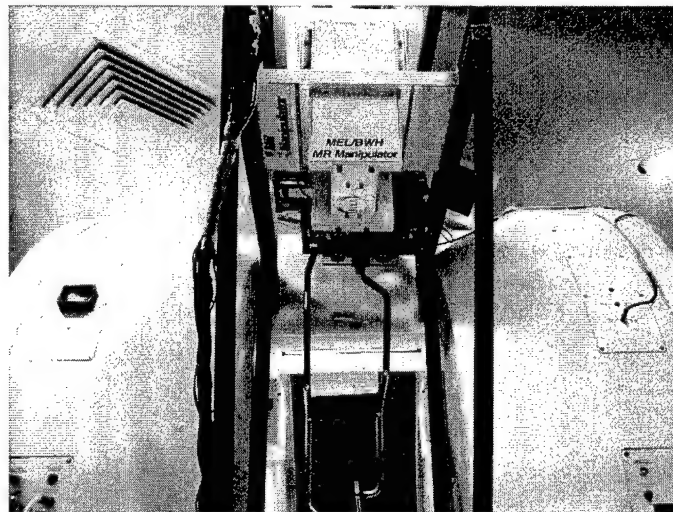
Figure 5: MRI compatible robot in interventional MRI system
(courtesy of Kiyoyuki Chinzei, AIST, Japan, and Ron Kikinis, BWH, USA)

Finally, researchers in Germany have developed an MRI compatible robotic biopsy system, focusing on breast cancer as an initial application. In vitro experiments using pig livers in a 1.5 Tesla magnet and 4 mm targets resulted in all eight targets being successfully hit [28].

3.2 *Orthopedic*

Orthopedics is well suited for robotic assistance due to the rigid nature of bone. Because bone does not deform significantly when it is drilled or cut, it is possible to intraoperatively apply preoperative imaging and planning information more easily than for soft tissues such as the brain or abdominal organs [29]. Orthopedics was also an early adopter of robotics, as the ROBODOC system described next was used to assist surgeons in performing part of a total hip replacement in 1992. This marked the first use of an active robot for hip surgery as the robot was used to mill out the hole for the hip implant.

3.2.1 **ROBODOC**

The ROBODOC system was developed clinically by Integrated Surgical Systems (ISS) for total hip replacement procedures from a prototype created at IBM Research. The system was used in over 1000 cases at a Frankfurt, Germany hospital from 1994 until 1998 [30]. The system consists of three major components: a planning workstation, the robot itself that does the cutting, and the workstation that guides and controls the robot.

A typical hip replacement procedure using ROBODOC is carried out as follows [31]. The procedure starts with the surgeon implanting three locator pins into the hip. These pins are later used as fiducial points for registering the patient anatomy with the robot. A CT scan is then obtained and the CT data is transferred to the planning workstation (ORTHODOC). The surgeon can then choose a suitable implant from a library of possible implants. The surgeon can virtually position the implant on the planning workstation, check different positions, and assess the impact on anteversion, neck length, and stress loading (Figure 6). When the planning session is finished, the data is transferred to the computer that controls ROBODOC.

In the operating room, the hip joint is exposed and the robotic system is moved into position to mill out the femoral cavity. The locator pins are used to register the hip joint with the robot. Cutting time is between 20-35 minutes, and the surgeon monitors this process by watching a computer screen which shows the progress of the cutting operation. The robot can also be stopped at any time. When the milling is complete, the robot is removed and the rest of the operation is completed by hand in the conventional manner. A photograph of ROBODOC milling the cavity for the implant is shown in Figure 7.
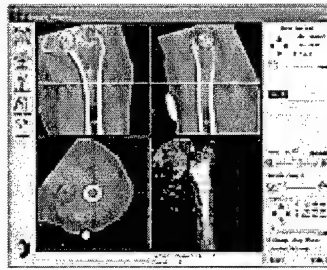
Figure 6: ORTHODOC planning workstation
(courtesy of Integrated Surgical Systems, USA)
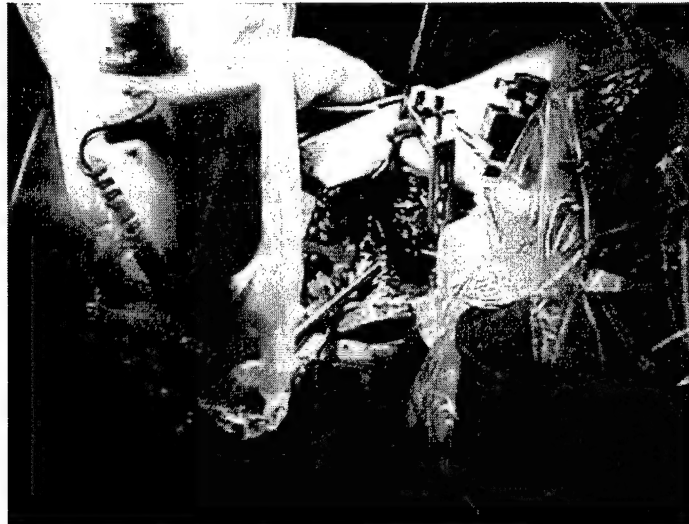
Figure 7: ROBODOC milling implant cavity for hip replacement surgery
(courtesy of Integrated Surgical Systems, USA)

3.2.2 Georgetown University/Johns Hopkins Collaboration

At Georgetown University Medical Center, our research group has been focusing on the use of robots for precision placement of instruments in minimally invasive spine procedures [16, 17]. This work is a collaboration with the Urology Robotics Laboratory of the Johns Hopkins Medical Institutions and the Computer Integrated Surgical Systems and Technology (CISST) Engineering Research Center at Johns Hopkins University.

Low back pain is a common medical problem, and minimally invasive procedures such as nerve blocks are rapidly growing in popularity as a potential method of treatment. To assist the physician in needle placement during these procedures, we have begun to use a newly developed version of the PAKY/RCM needle driver robot developed at the Urology Robotics Laboratory. Robotic systems such as these have great potential as physician assist devices for improving the precision of needle placement and enabling the development of the next generation of precision guidance systems for interventional techniques.

The newly developed needle driver robot consists of a 3 degrees of freedom (DOF) translational stage, a 7 DOF passive positioning stage, and a 3 DOF orientation/driving stage. The robot is mounted on the interventional table and the physician controls the system through a touch screen/joystick interface as shown in Figure 8. A cadaver study has been done (Figure 9) and institutional approvals for human studies are nearly complete. Clinical trials to use the robot to place a 22-gauge needle for nerve and facet blocks in the spine are expected to begin by early 2002.
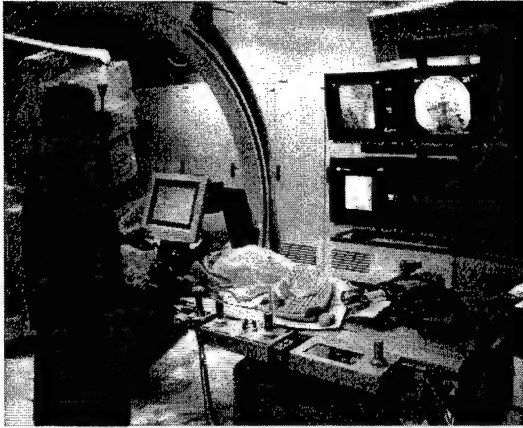
Figure 8: Needle driver robot cadaver study. Physician uses touch screen/joystick interface to control the robot and monitors the intervention on the fluoroscopy screens.

Figure 9: Close-up of cadaver study showing needle driver and passive positioning arm.

3.2.3   University of Tokyo/Johns Hopkins Collaboration
An integrated robotic system for percutaneous placement of needles under CT guidance was developed by Masamune at the University of Tokyo in collaboration with Johns Hopkins. Single image based co-registration of the PAKY/RCM robot and image space was achieved by stereotactic localization using a miniature version of the BRW head-frame built into the radiolucent needle driver. A phantom study was done with an orientation accuracy of 0.6 degrees and a needle tip to target distance of 1.04 mm. The system is applicable to orthopedic (spine) and many other percutaneous procedures. For further details, see the article by Masamune in this special issue [32].

3.2.4   Marconi Medical Systems
An active robot has been integrated with a CT scanner for interventional procedures by Yanof and colleagues at Marconi Medical Systems. Animal experiments using pigs were completed to investigate needle placement in the abdomen. The path was planned based on the CT scans and this information was sent to the robot, which automatically moved to the skin entry point and then oriented and drove the needle. For further details, see the article by Yanof in this special issue [33].

3.2.5   Imperial College
A special purpose robot called Acrobot (for active constraint robot) has been developed for safe use in the operating room for total knee replacement surgery. The surgeon guides the robot using a handle attached to a force sensor attached to the robot tip. Following

two preliminary clinical trials, the first clinical trial was conducted in which the Acrobot was used to register and cut the knee bones. For further details, see the article by Jakopec in this special issue [34].

3.3 Urology

3.3.1 Prostate Resection

One of the pioneering research groups in Medical Robotics is the Mechantronics in Medicine Laboratory at Imperial College in London. Starting in 1988, the group began developing a robotic system named the *Probot* to aid in transurethral resection of the prostate [18]. While an initial feasibility study was carried out using a standard six-axis PUMA industrial robot, such a system was determined not to be practical for medical purposes as these robots are not designed to work in close proximity with humans. Therefore, a special purpose robotic frame was designed to hold the surgical instrument. The first patient was treated in April 1991 and this was the first use of a robot to remove substantial quantities of tissue from a human patient [2].

The robotic frame shown in Figure 10 consists of three axes of movement. An additional axis is provided by the resectoscope, which is the surgical instrument used to remove the tissue. The geometry of the system is designed to allow a cavity to be hollowed out from within the prostate and restrict movements outside an allowable range. This restriction provides an additional margin of safety.
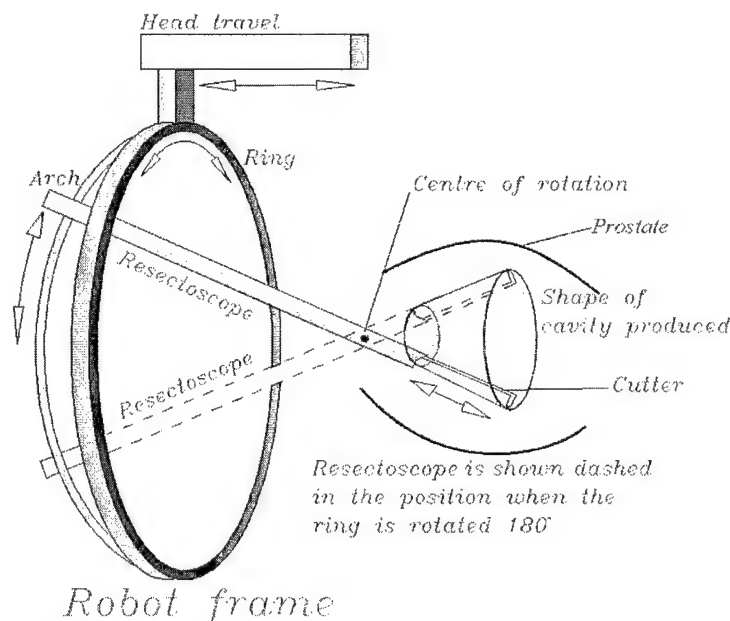
Figure 10: Prostate robot frame
(courtesy of Brian Davies, Imperial College, London)

The clinical application consists of four stages: 1) measurement; 2) imaging; 3) cavity design; and 4) cutting. To begin the procedure, the patient is positioned on the operating

table and the Probot is positioned at the bladder neck. The user interface allows the surgeon to view the internal anatomy from a video camera within the resectoscope. An ultrasound probe is then passed down the resectoscope and the robot is set to acquire a series of scans at 5 mm intervals to build up a 3D image of the prostate. The surgeon can then outline the cavity to cut on each slice of the ultrasound image using a light pen. The final step is the actual cutting operation. A picture of the operating room and Probot in clinical use is shown in Figure 11. The surgeon is sitting to the left and can observe the progress of the cutting on a video monitor as shown in Figure 12. The real-time image of the prostate is at the top left of the monitor and an overlay of the cuts on an ultrasound image is shown at the bottom right.

Figure 11: Probot in clinical use
(courtesy of Brian Davies, Imperial College, London)

Figure 12: Video monitor display during procedure
(courtesy of Brian Davies, Imperial College, London)

3.3.2 Urology Robotics Laboratory

The Urology Robotics (URobotics) laboratory is a part of the Urology Department at Johns Hopkins Medical Institutions and is dedicated to the development of new technology for urologic surgery. The program combines engineering and medical personnel in close cooperation and is the only academic engineering program devoted exclusively to urology. This group and colleagues at the Engineering Research Center at Johns Hopkins University have developed the PAKY (percutaneous access of the kidney) needle driver [35] and RCM (remote center of motion) robot [36] which has been applied to minimally invasive kidney procedures. Further details about this project and other work at the Urology Robotics Laboratory can be found in the article by the laboratory director, Dan Stoianovici, in this special issue [37].

3.4 Maxillofacial

Maxillofacial surgery is a branch of surgery that is concerned primarily with operations on the jaws and surrounding soft tissues. In many cases in maxillofacial surgery it is necessary to manipulate the skull bone including drilling, cutting, shaping, and repositioning operations. Accuracy is at a premium since the shape of the bone and the esthetic appearance of the skull and face are extremely important to patients. The current procedures are done manually using tools such as pliers, chisels, and electric saws and drills. Maxillofacial surgery may be a good application area for robotics since primarily bony structures are involved and accuracy is at a premium [19].

For example, the following clinical tasks must be supported by a robot in maxillofacial surgery: [38]
1. Guidance for non-flexible catheter implantation (brachytherapy)
2. Handling of electric drills, taps, and screwdrivers for fixing bones and implants (anaplastology)
3. Handling of electric saw and retractor hooks

3.4.1 Experimental Operating Room

For developing an interactive robot system for maxillofacial surgery, an experimental operating room has been set up at the Charite Hospital of Humbolt University in Berlin, Germany [19] as shown in Figure 13. This operating room includes a unique robotic system, the SurgiScope. While most robotic systems described in this review are based on a serial kinematic structure in which the links are attached one after the other as in the human arm, at least one company has developed a medical robot based on a parallel kinematic structure. The SurgiScope is a general purpose six degree-of-freedom robotic device consisting of a fixed base, three parallel links, and a movable end-effector. The system is designed to be fixed on the ceiling and provides a large workspace while not cluttering the operating room floor. The parallel kinematic structure also provides a very stable structure for precision operations. The robot was originally sold by Elekta, but is now being marketed by Jojumarie Intelligente Instrumente in Berlin. The use of this system for placement of the radiation source in brachytherapy in animal studies in described in [39].
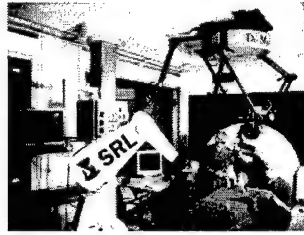
**Figure 13: Surgical robotics laboratory showing parallel robot (ceiling mounted),
mobile CT (back of photo), and serial robotics arm (foreground)**
(courtesy of Tim Lueth, Charite Berlin).

3.4.2   Craniofacial Osteotomy

Another system for maxillofacial surgery has been developed at the Institute of Process
Control and Robotics in Karlsruhe, Germany, in cooperation with the Clinic of
Craniofacial Surgery at the University of Heidelberg. Animal studies were carried out to
perform osteotomies where an RX 90 surgical robot (Orto Maquet, Staubli) was used to
guide a surgical cutting saw [20]. The studies were carried out as follows. Twelve
titanium screws were implanted into the head of a pig to be used as landmarks. A CT
scan with 1.5 mm slice spacing was done, and the resulting images were used to create a
surface model for surgical planning. A haptic interface was used to trace the cutting lines
on the surface of the skull (Figure 14). Once the planning was completed, the robot was
registered with the pig in the operating room (Figure 15), and the surgeon manually
guided the robot arm along the trajectory where his movements perpendicular to the
cutting line were restricted. This system has also been evaluated using sheep for the
autonomous milling of a cavity in the skull needed for a customized titanium implant.
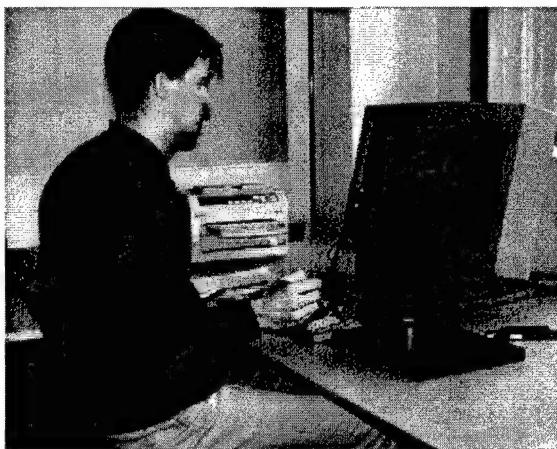
**Figure 14: Planning of the bone cuts
using a haptic interface**
(courtesy of Catherina Burghart, University of
Karlsruhe, Germany)

**Figure 15: Registration by force controlled
manual guiding of the robot arm**
(courtesy of Catherina Burghart, University of
Karlsruhe, Germany)

3.5 Radiosurgery

Radiation is a common means of treatment for tumors. Radiosurgery is the delivery of radiation to a tumor while attempting to spare adjacent normal tissue. In the brain, radiosurgery has typically been carried out using stereotactic frames that are rigidly fixed to the patient's skull. A novel method for precision irradiation called image-guided radiosurgery has been developed by Adler and associates at Stanford University (California, U.S.A.) [21]. The system consists of a lightweight linear accelerator, a Kuka robot, paired orthogonal x-ray imagers, and a treatment couch as shown in Figure 16. During a radiosurgery treatment session, the x-ray imaging system determines the location of the lesion. These coordinates are sent to the robot, which adjusts the pointing of the accelerator beam towards the lesion. The robot arm moves the beam through a series of preset positions to maximize the dose to the lesion while minimizing the dose to the surrounding normal tissue.
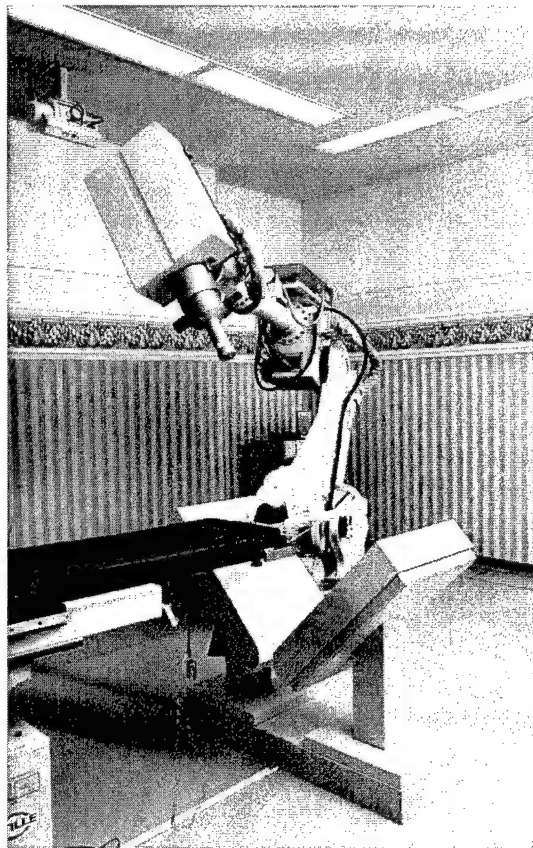
Figure 16: CyberKnife robotic radiosurgery system
(courtesy of Accuray, USA)

3.6 Ophthalmology

There are many surgical operations on the eye, ear, brain, nerves, and blood vessels that require extremely precise positioning and manipulation of surgical instruments. It is not uncommon for a microsurgeon to perform 150-200 um movements during an operation

and smaller movements would be desirable [40]. One representative microsurgical application is eye surgery and prototype systems for this purpose have been developed by Das [41] and Hunter [42].

Taylor and colleagues at Johns Hopkins University recently developed a "Steady-Hand" robot for microsurgical augmentation [22] as shown in Figure 17. While the initial target application is eye surgery, the system is applicable to numerous clinical specialties. The system consists of four modular sub-assemblies:
1. an off-the-shelf XYZ translation assembly (only the Z-axis can be seen here)
2. an orientation assembly
3. an end-of-arm motion and guiding assembly including a force/torque sensor
4. specialized instruments

The major difference between this robotic device and the other robotic systems described in this review is that the Steady-Hand robot is designed to work cooperatively with the physician. In operation, the physician will grasp the tool held by the robot and manipulate the tool with the aid of the robot. The control system of the robot senses the forces exerted by the physician on the tool and by the tool on the environment and responds accordingly. The robot can thus provide smooth, tremor-free, precise positioning and force scaling.

The Steady-Hand robot was employed in a series of experiments to test the ability of a human to position a 10-0 microsurgical needle to 250, 200, and 150 micrometer accuracy [43]. A datum surface was fabricated consisting of two metallic sheets separated by an insulating surface. Three different versions of the experiments were performed: 1) unassisted series (human only); 2) hand-held (human plus Steady-Hand); and 3) autonomous (Steady-Hand was registered to the plates). The use of the Steady-Hand robot was found to significantly improve the ability of the human to position the needle, as success rates improved from 43% unassisted to 79% hand-held for the 150 micrometer holes (autonomous performance was even better at 96.5%).
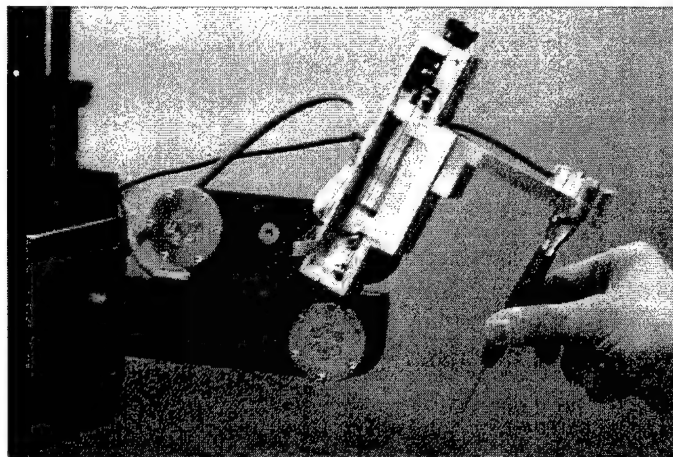

Figure 17: Steady-Hand robot for microsurgical augmentation
(courtesy of Russell Taylor, Johns Hopkins University, USA)

3.7 Cardiac

Two companies have recently developed master-slave systems for minimally invasive surgery which are aimed at restoring the dexterity that is lost when using traditional laproscopic instruments. The introduction of these systems is a paradigm shift for surgical applications, in that the physician is no longer directly manipulating the surgical tool, but rather controlling the device from a remote interface. While these systems might be used for remote telesurgery in the future, in current practice the master and slave devices are in the same operating room. The initial clinical applications of these systems have been in cardiac surgery, although other applications are beginning to appear as well.

3.7.1 Intuitive Surgical: da Vinci

The Intuitive Surgical system (Figure 18), called da Vinci, consists of the surgeon's viewing and control console, a control unit, and a three-arm surgical manipulator [23]. The system is designed to combine the freehand movements used in open surgery with the less traumatic methods of minimally invasive surgery. The surgeon sits at the console and sees a high-resolution, three-dimensional (3D) image of the surgical field. The surgeon's hands grasp the instrument handles that control the remote endoscopic manipulators and end-effectors. The surgeon's console is shown in Figure 18 and a view of the instrument handles along with the remote manipulators is shown in Figure 19. The manipulators provide three degrees of freedom (pitch, yaw, and insertion) and the end-effector consists of a miniature wrist that adds three more degrees of freedom (pitch, yaw, and roll) and one motion for tool actuation (such as grip). The system allows increased precision by providing motion scaling whereby large motions of the input devices can be scaled down proportionally to produce small motions at the end-effector. Finally, unintended movements caused by tremor, which typically occur with a frequency of 6-10 Hz, are filtered by applying a 6 Hz motion filter [44]. Design issues associated with these types of systems are described by Madhani [45].
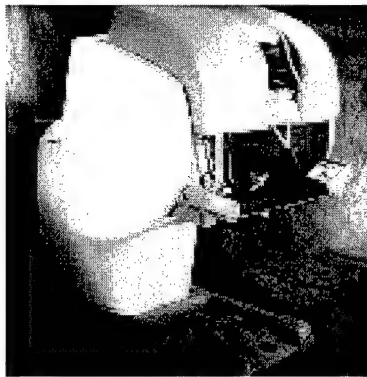
Figure 18: da Vinci surgeon's console
(courtesy of Intuitive Surgical, USA)
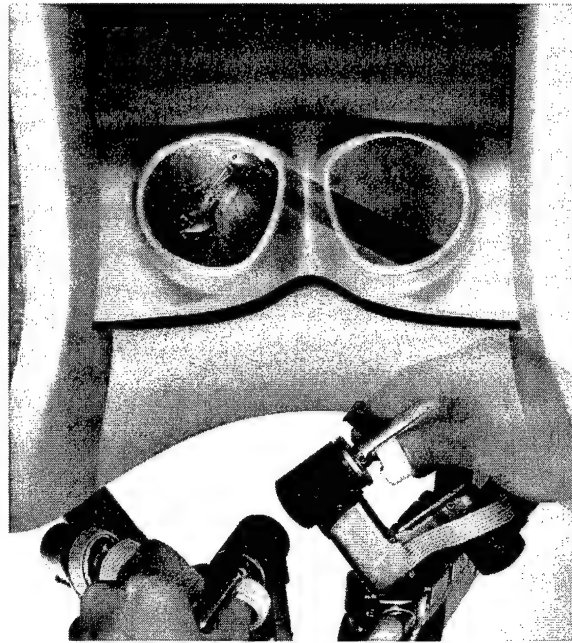
Figure 19: da Vinci instrument handles and remote manipulators
(courtesy of Intuitive Surgical, USA)

The da Vinci system has been used to perform over 500 procedures as of October 1999 [23]. The system has not only been used for cardiac procedures such as fully endoscopic coronary artery bypass grafts (CABG), but has also been used for a wide variety of other procedures including Nissen fundoplication, cholecystecomy, and lumbar sympathectomy.

3.7.2 Computer Motion: Zeus

A similar telesurgical system, called Zeus, has been developed by Computer Motion. A picture of the surgeon's console is shown in Figure 20. The Zeus slave system consists of three interactive robotic arms (two endoscopic instrument arms and one endoscopic camera arm) which are mounted on the operating room table. However, while the Intuitive Surgical system is a six degree of freedom system (plus grip motion), the Computer Motion system only has four degrees of freedom, and therefore is not as dexterous. Still, the performance of these systems in clinical applications is just beginning to be investigated, and it is difficult to draw conclusions about their efficacy at this point.

The clinical use of the system for endoscopic coronary artery bypass on 25 patients has been described by Boehm [24]. This study showed that endoscopic coronary artery bypass on the beating heart is possible, but further development of the technology and techniques is required to minimize the procedure time.
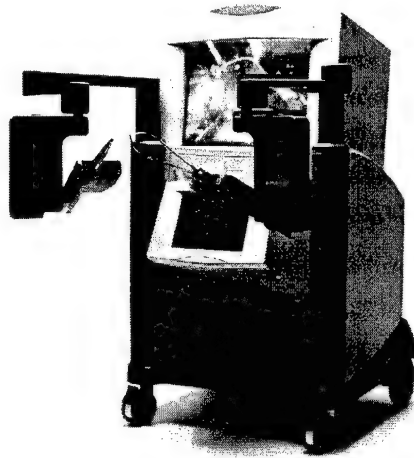
Figure 20: Zeus surgeon's console
(©2001 Computer Motion, USA. Photograph by Bobbi Bennett).

3.7.3   Grenoble: Pericardial Puncture

A prototype robot for pericardial puncture has been developed by Troccaz and colleagues at the TIMC/IMAG laboratory of Grenoble University Hospital. The robot is a six degree of freedom SCARA design consisting of a vertical translational axis, three vertical rotational axes, a rotation about a horizontal axis, and a last modular joint which can be a rotational or translational axis. The robot is designed as a "syngergistic" device that is to be used in cooperation with a human operator. For further details, see the article by Schneider and Troccaz in this special issue [46].

4.0   Technology Challenges / Research Areas

While a number of different clinical areas are being explored as noted in Section 3, the field of medical robotics is still in its infancy and we are just at the beginning of this era. Only a handful of commercial companies exist and the number of medical robots sold each year is very small. Part of the reason for this is that the medical environment is a very complex one and the introduction of new technology is difficult. In addition, the completion of a medical robotics project requires a partnership between engineers and clinicians which is not easy to establish.

Technology challenges and research areas for medical robotics include both the development of system components and the development of systems as a whole. In terms of system components, research is needed in:
1. system architecture
2. software design
3. mechanical design
4. imaging compatible designs
5. user interface
6. safety

For medical robotics systems, the development of application testbeds is critical to move the field forward. These testbeds can also serve to improve the dialog between engineers and clinicians. However, at least in the U.S., it is difficult to get funding to develop these testbeds. Governmental funding agencies such as NIH or NSF will usually not fund such efforts as they are geared more towards basic research rather than applied research and development. Manufacturers are usually not interested because the environment and investment payback for medical robotics is uncertain. The regulatory issues for medical robotics have not been fully explored, although several systems have been FDA approved. These factors remain obstacles to advancing the field.

In the following sections, each of the six system components listed above are briefly discussed.

4.1 System Architecture

For medical robotics to evolve as its own field and for the cost and difficulty of developing prototype systems to decrease, the establishment of a system architecture would be an enabling step. The systems architecture should emphasize modularity, as noted by Taylor in the design of the Steady-Hand robot, which emphasizes modularity in mechanical design, control system electronics, and software [22]. A modular approach has also been emphasized in the Urology Robotics laboratory of Stoianovici [37], where a number of mechanical modules have been developed for precision interventional procedures.

4.2 Software Design

The development of a software environment for medical robotics, possibly including an appropriate real-time operating system, is a significant challenge. Many researchers developing medical robotics system base their software development on commercially available software packages that may not be suitable for the surgical environment. However, the low cost and widespread availability of these software packages makes their use attractive and there are steps that can be taken (such as watchdog timers, backup systems, and error recovery procedures) to make these systems more reliable. Still, it is believed that along with the system architecture mentioned above, a robust software environment geared to the medical environment would be a substantial contribution. While this software environment would still need to be customized for different surgical procedures, researchers would at least have a starting point for their development work.

4.3 Mechanical Design

In addition to better software design, novel mechanical designs are needed to improve the utility of robotics in medical procedures. As noted in the historical review in this paper, the first recorded medical application of a robot was for biopsy of the brain, using a standard PUMA industrial robot. While some other researchers have described the use of industrial robot for medical tasks, it is the belief of these authors and others (see [2] for

example) that special purpose mechanical designs are more appropriate for most applications. In particular, these designs should be safer, as they can be designed specifically for the medical environment and customized for different medical procedures. Novel mechanical designs presented in this review include the Probot [18] and the Steady-Hand robot [22]. However, it should be noted that special purpose designs will not enjoy the same economies of scale as more general designs, and one other solution may be to develop more general purpose medical robots with specialized end-effectors.

4.4 Imaging Compatible Systems

With the increasing popularity of image-guided interventions, robotic systems are required that can work within the constraints of various imaging modalities such as CT and MRI. While these systems are for the most part still under the direct control of the physician, in the future they will be increasingly linked to these imaging modalities. In this review, some systems were noted that fall within this category, such as the MRI compatible manipulator of Masamune [15] and the CT integrated robot Minerva [13].

4.5 User Interface

One question that arises in the development of all medical robotics systems concerns the user interface. What is a suitable user interface for a medical robot? Should the robot be given a commanded path or volume and then autonomously carry out the task? Is a joystick or pushbutton interface appropriate? Or would the physician rather manipulate the tool directly with the assistance of the robot? Is force feedback required for a high fidelity user interface?

These are all questions that require further investigation by the medical robotics community. The answer certainly will vary depending on the medical task for which the robot is designed. It seems that medical robots will at least initially be more accepted by physicians if the physicians feel that they are still in control of the entire procedure.

4.6 Safety Issues

Safety is a paramount concern in the application of these systems. This is an area that must be addressed to move the field forward. Safety issues have been discussed by Davies [47] and Elder and Knight [48]. According to Davies, medical robotics is a completely different application from industrial robotics in that medical robots must operate in cooperation with people to be fully effective. Therefore, appropriate safety levels should be defined and discussed by the community at large. Safety measures that can be taken include the use of redundant sensors, the design of special-purpose robots whose capabilities are tailored to the task at hand, and the use of fail-safe techniques so that if the robot does fail it can be removed and the procedure completed by hand. One other safety issue for medical robotics is the need for sterilization and infection control in the operating room and interventional suite.

Davies also presents a hierarchical scheme for the host of tools available to surgeons, ranging from hand-held tools to a fully powered autonomous robot. As the hierarchy moves towards autonomous robots, the surgeon is less and less in control, and more dependent on the mechanical and software systems of the robot. Davies contends that until a consensus is developed on what level of safety is acceptable for what level of autonomy, the medical manufacturers will be slow to develop robotic systems.

While mechanical constraints are one means of assuring safety, programmable constraints, while inherently not as safe, are more flexible. The idea is to dynamically constrain the range of possible motions [4, 46]. Four programming modes can be envisioned: free mode, position mode, trajectory mode, and region mode. As an example, region mode is particularly suited to resection operations such as total knee replacement in that the surgical tool is constrained to remain within a pre-defined region. This mode could also be valuable in training of residents and fellows.

5.0 Conclusions

This paper has reviewed the state of the art in surgical robotics. Several prototype and commercial medical robotics systems were described. Technology challenges and areas for future research were discussed. The use of robots in medicine clearly offers great promise.

We are just in the initial stages of the application of robotics to medicine, and much more work remains to be done. In particular, the development of more testbeds is required for different medical procedures so that more experience with the technology and how it can be integrated into clinical practice can be gained. The issues of cost, safety, and patient outcomes also need to be considered. While there have been some modestly successful commercial medical robots such as ROBODOC and da Vinci, they still are not completely accepted by the medical community.

It may be that the full benefits of robots in medicine will not appear until more integrated systems are developed, in which the robots are linked to the imaging modalities or to the patient anatomy directly. This link will highlight the potential advantages of robots such as the ability to follow respiratory motion, and enable physicians to successfully complete procedures that can only be imagined today.

6.0 Acknowledgements

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10.2.4   Cleary 2001b: Robot Cadaver Study

Reprint begins on the next page and is 6 pages.

Robotically Assisted Perispinal Nerve and Facet Blocks: A Cadaveric Study

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1 Abstract

PURPOSE: To evaluate the feasibility of using a joystick controlled robotic needle driver
to place a 22-gauge needle for perispinal nerve and facet blocks.

MATERIALS AND METHODS: Bi-plane fluoroscopy and a robotic needle driver were
used to place 12 needles into the lumbar perispinal region of a 98 year-old female
embalmed cadaver. Small metal BB nipple markers 1 mm in diameter were
percutaneously inserted to serve as targets. Six needles were then placed near the nerve
root and six needles were placed near the facet root. Anterior-posterior and lateral
radiographs were obtained after each placement to assess the accuracy of placement.

RESULTS: All needles were placed within 3 mm of the target BB. The average
placement accuracy was 1.44 mm and the standard deviation was 0.66 mm.

CONCLUSION: A robotic needle driver can be used to accurately place needles in the
nerve and facet regions. Clinical studies are required to investigate the advantages and
disadvantages of this system for interventional needle procedures.

2 Introduction and System Description

For the past two years, our research group has been investigating technology
developments to assist the physician in improving the precision of minimally invasive
spine techniques. As part of this research, we have been collaborating with the Urology
Robotics Laboratory of Johns Hopkins Medical Institutions to apply a "needle driver"
robot in spine interventions. A new version of this robotic system was completed by
Johns Hopkins in July 2001. A photograph of the new robot is shown in Figure 1. A
cadaver study to investigate the feasibility of using this device to place needles in the
perispinal region was conducted at Georgetown University on 1 September 2001. The
results of this cadaver study are reported here.

Before undertaking the cadaver study, the basic operation of the robot was verified on a
component by component basis in the Urology Robotics Laboratory during system
manufacture and assembly. After the engineering performance of the system was

verified, the system was brought to Georgetown to begin clinical evaluation. The robotic system was first tested in the interventional suite at Georgetown by placing needles into a cantaloupe as shown in Figure 2. The robot is mounted on the interventional table using a custom-designed locking mechanism. The robot is positioned initially near the skin entry point by loosening the passive gross positioning mechanism and moving the needle driver end of the robot by hand. Once this initial position has been attained, this mechanism is locked and the robot is switched to physician control.

The physician controls the robot by manipulating the joystick on the control panel. Different modes of operation, such as translational motion of the entire unit or rotational motion of the end-effector, can be selected. The system was intentionally designed to limit motion to one mode at a time to make it easier for the physician to understand the action of the joystick. An emergency stop button is prominently located next to the joystick as a precaution. The system may be shut down at any time using this button. The physician remains in control of the device at all times and may revert to the current manual technique at any time.

The robot controller is housed in an industrial PC chassis and contains all the electronics and safety monitoring devices. The robot controller includes several safety features, including a watchdog timer board that is used to regularly monitor the system operation. The controller is placed out of the way at the back of the interventional suite and is connected to the robot by cables with a length of 20 feet.

3   Cadaver Study Report

3.1   Materials and Methods

A 98 year old embalmed average size female cadaver was placed on the interventional table in a supine position. To serve as targets, 1 mm metal BBs (nipple markers: Figure 3) were placed in the lumbar spine from L1 to L4. A total of twelve BBs were placed as shown in Table 1. Six BBs were placed on each side, and the locations were chosen to be as close to the nerve root and facet as possible. The BBs were placed using a 22 gauge 5 inch spiral needle (Becton Dickinson and Co).

The imaging equipment used for this study was the same equipment used in routine clinical practice, a Siemens NeuroStar T.O.P. This is a biplane digital angiography unit with rotational angiography capabilities.

After the cadaver was placed, the robot was mounted on the table using a special purpose mount developed by Johns Hopkins. The operation of the robot by the physician through a joystick is shown in Figure 4. A view from the other end of the room is shown in Figure 5.

Table 1: Study Results

Trial number	Level	Distance from target (A/P fluoroscopy) mm	Distance from target (lateral fluoroscopy) mm	Distance from target (root mean square distance) mm
Nerve 1	Right 4	1.10	1.70	2.02
Nerve 2	Right 3	0.00	1.71	1.71
Nerve 3	Right 2	0.00	0.80	0.80
Nerve 4	Left 2	1.75	1.34	2.20
Nerve 5	Left 3	2.50	0.19	2.51
Nerve 6	Left 4	1.40	0.74	1.58
Facet 1	L1-2 Left	0.26	0.29	0.39
Facet 2	L2-3 Left	0.96	1.53	1.81
Facet 3	L3-4 Left	1.49	0.19	1.50
Facet 4	L3-4 Right	0.70	0.13	0.71
Facet 5	L2-3 Right	0.80	0.00	0.80
Facet 6	L1-2 Right	0.00	1.19	1.19
Average		0.91	0.82	1.44
Standard deviation		0.79	0.65	0.66

Note: RMS distance calculated from square root of (A/P squared + lateral squared)

Once the targets were placed, the robotic device was used along with a 22 gauge needle in an attempt to position the needle to within 3 mm of the target (3 mm was the distance chosen as reasonable for this study by Dr. Watson and approved in the IRB protocol). The typical scenario was as follows. The passive arm was unlocked and the needle tip was placed within a few centimeters of the skin entry point above the target area. The robot was then set to translational mode by selecting this mode on the touch screen. Using the joystick for control, the physician then moved the tip of the needle to the skin entry point while monitoring the position of the robot by direct vision. The robot was then set to rotational mode by selecting this mode on the touch screen. Using the joystick once again, the physician then oriented the needle to point towards the target point while monitoring the orientation using A/P fluoroscopy. When the physician was satisfied that the needle was pointing toward the target, the robot was then set to needle drive mode by selecting this mode on the touch screen. Using the joystick once again, the physician drove the needle toward the target while monitoring the needle depth and trajectory using lateral fluoroscopy.

As each needle was placed, the corresponding A/P and lateral fluoroscopy images were saved in digital format for follow-up analysis. The level, type of block (nerve or facet), and corresponding images were recorded by Dr. Cleary, who served as an observer during the study. After the study, the images were analyzed by Mr. Lindisch and the distance from the target to the needle on both A/P and lateral fluoroscopy was recorded.

The images were sent in the DICOM format from the Siemens Neurostar to a desktop computer running the PiView medical imaging software. Each image can then be viewed in PiView and the distance from the center of the target to the center of the needle can be measured by the software[1]. This was done for all 24 images (A/P and lateral from each of the 12 blocks). Representative results for nerve block 4 and facet block 2 are shown in Figures 7-10.

3.2 Results

The results of the accuracy study are given in Table 1 above. The average placement accuracy was 1.44 mm and the standard deviation was 0.66 mm. In most cases the physician was able to drive the needle directly toward the target. However, in some cases the needle deviated slightly and the physician needed to correct the needle path. This was done by re-orienting the needle slightly in the direction opposite the deviation. When the needle was then driven further into the body, the path would then generally move closer to the target.

3.3 Conclusions

Based on the study data reported here, it is feasible to use a physician controlled robotic needle driver to accurately place needles in the nerve and facet regions of the spine.

4 Acknowledgements

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[1] It should be noted that two assumptions are made in making these measurements and calculating the distance. First, it is assumed that the measurement scale on the PiView imaging software is correct to within 10%. This scale is based on the pixel to mm value from the DICOM header in each image. This value comes from the Siemens Neurostar system and is based on a measurement plane near the isocenter of each C-arm. It is our experience that objects near the isocenter like those measured here will be within 10% of the measured values. Second, to calculate RMS values, we assume that the A/P and lateral views are orthogonal. This is a good assumption for this cadaver study.
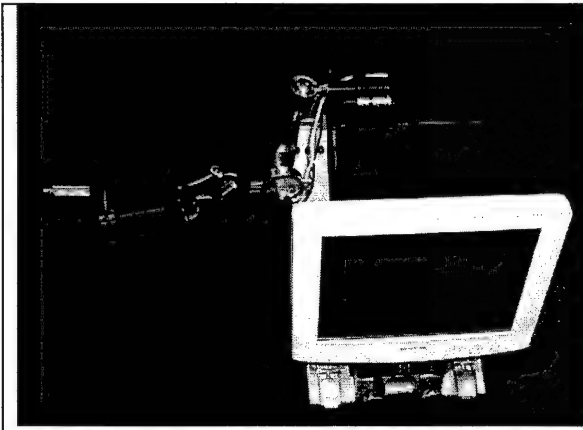
Figure 1: Robot showing touch screen, translational mechanism, and needle driver end-effector
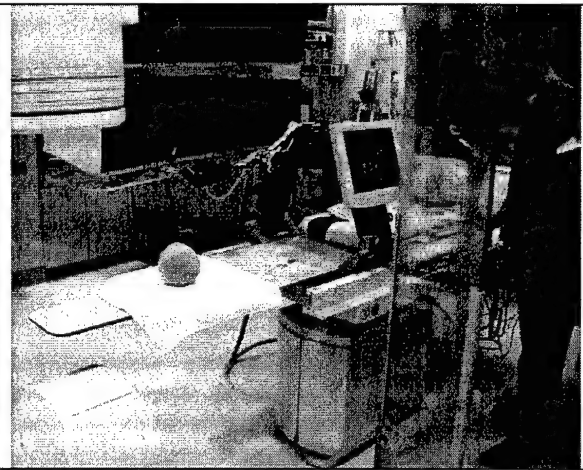
Figure 2: Interventional suite during engineering trials and cantaloupe puncture tests
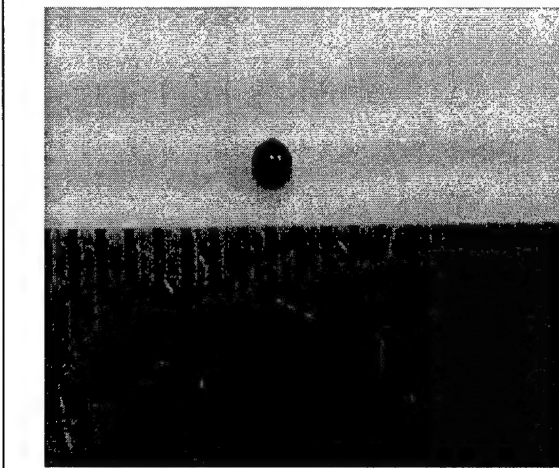
Figure 3: Target metal BBs 1 mm in diameter
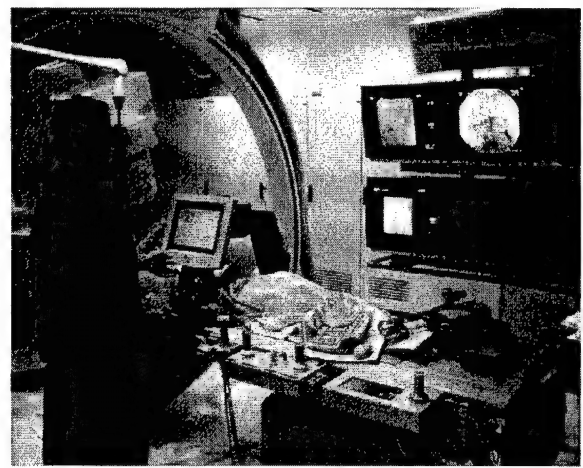
Figure 4: Cadaver study and physician operating joystick to control robot
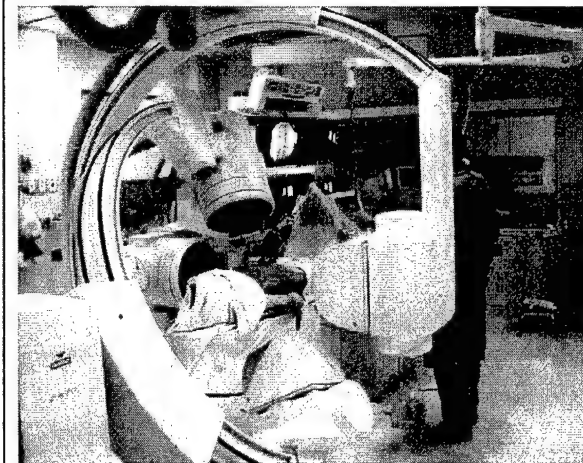
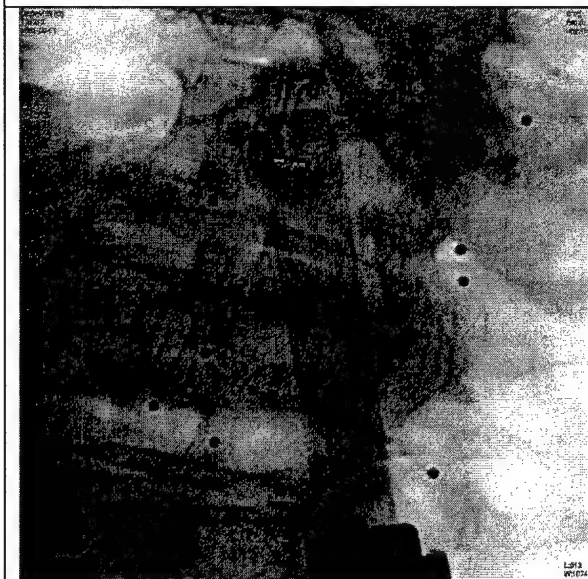**Figure 5: Cadaver study room view end showing physician and fluoroscopy monitors**
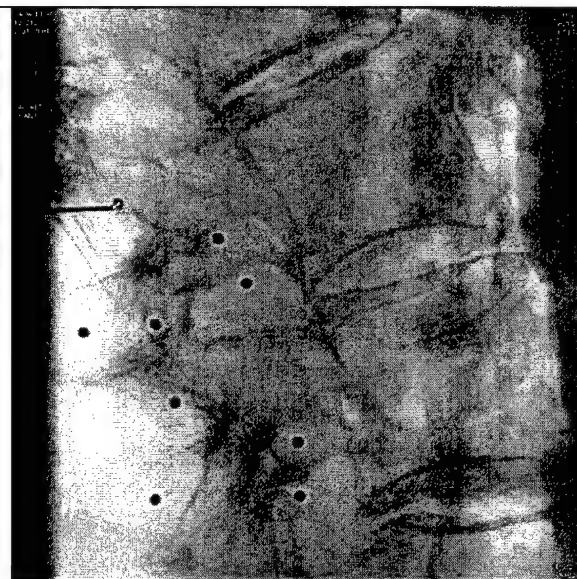

Figure 6: Close-up view of robot and cadaver

Figure 7: A/P fluoroscopy image for nerve block 4 (needle to bb distance of 1.75 mm)

Figure 8: Lateral fluoroscopy image for nerve block 4 (needle to bb distance of 1.34 mm)

Figure 9: A/P fluoroscopy image for facet block 1 (needle to bb distance of 0.26 mm)

Figure 10: Lateral fluoroscopy image for facet block 1 (needle to bb distance of 0.29 mm)

10.2.5   Cleary 2001c: Automatic Registration

Reprint begins on the next page and is 1 page.

Automatic Registration for Percutaneous Vertebral Body Tracking

Kevin Cleary, PhD[a]; Sheng Xu, BS[b]; Gabor Fichtinger, PhD[b]; Neil Glossop, PhD[c]

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1. OVERVIEW

The registration of cross-sectional medical images with patient anatomy is an important problem in image-guided surgery. Current registration methods such as paired-point matching can be tedious and require large incisions. Improved methods of registration for percutaneous spine procedures could potentially improve the accuracy of minimally invasive spine procedures. In this poster, we will describe a combination of hardware and software for the automatic registration of a vertebral body with cross-sectional medical images. The technique is based on a fiducial carrier attached directly to the spinous process and does not require the user to identify anatomical landmarks.

2. METHODS

The fiducial carrier is a plastic tracking frame (Traxtal Technologies, Toronto, Canada) containing nine radio-opaque fiducials. The frame also holds three passive retro-reflective spheres, which can be automatically tracked by an infrared camera localizer (hybrid Polaris, Northern Digital, Waterloo, Canada). For these tests, the carrier was rigidly attached to the spinous process of an abdominal interventional phantom (CIRS Inc., Norfolk, Virginia) using a locking pin. In a simulated biopsy procedure, the phantom was then placed on a CT table and a series of axial slices were scanned. These axial slices were then registered with the coordinate system of the localizer. This registration enables the operator to track any point on the phantom with a pointer and overlay the position of the pointer on the CT scans, as done in commercial image-guided surgery systems.

The registration process consists of the following steps: 1) thresholding; 2) connectivity checking; 3) fiducial identification; and 4) transformation matrix computation.

3. SUMMARY

The registration method has been implemented as part of a robotically assisted biopsy testbed incorporating a mobile CT scanner, an infrared camera, and a "needle driver" robot. Preliminary studies showed good correlation. More detailed experiments are in progress.

ACKNOWLEDGEMENTS

10.2.6   Cleary 2001d: Robot Biopsy Testbed

Reprint begins on the next page and is 7 pages.

CT-Directed Robotic Biopsy Testbed:
User Interface and Coordinate Transformations

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ABSTRACT

CT-guided percutaneous biopsy is a widely accepted practice in the medical field. Because efficient and safe CT-guided percutaneous interventions require accurate needle placement, there are limitations to the accuracy obtainable using freehand techniques, particularly for small or deeply situated target areas. In addition, CT-directed percutaneous biopsy can be tedious and time consuming, since frequent re-imaging may be required. As a demonstration platform, we are developing a robotic biopsy testbed incorporating a mobile CT scanner, a small "needle driver" robot, and a localizer. This testbed will be used to compare robotically assisted biopsy to the current manual technique. The testbed will also allow us to investigate software architectures for integrating various hardware and software components. This testbed is the first step in developing the robotically assisted biopsy system of the future. In this paper we present the overall concept and then provide details about the user interface and coordinate transformations.

KEYWORDS: medical robotics, biopsy, computed tomography, image guidance, localizer, user interface

1. INTRODUCTION

Minimally invasive spine procedures are increasingly popular due to improved techniques and the decreased trauma to the patient. Currently, percutaneous spine biopsy is performed by freehand passage of the biopsy needle from the skin surface to the spine. Based on imaging modalities such as CT, the physician identifies the skin entry point and the target, thus defining the desired needle trajectory. The physician then aligns the biopsy needle by hand and partially inserts it towards the target. The physician proceeds with further insertion of the biopsy needle, checking the position of the needle by re-scanning as necessary.

The main problem with this free hand technique is that the physician has limitations in accuracy when initially lining up the biopsy needle and then staying on course with the planned needle trajectory. Additionally, when the physician releases the needle, the needle can drift or tilt away from the desired path due to gravity, particularly when first starting the insertion.

Our goal is to develop a robotic assist system that is linked to the CT images to assist the physician in precision placement of the biopsy needle. This project is a collaboration between Georgetown University, the Urology Robotics Laboratory of Johns Hopkins Medical Institutions, the Center for Computer Integrated Surgical Systems and Technologies at Johns Hopkins University, and Traxtal Technologies.

Other researchers have developed biopsy systems to aid in biopsy tasks. These include passive positioning systems, which provide image guidance to assist the physician in orienting the biopsy needle, as well as semi-autonomous robots which position, drive, and guide the biopsy needle under remote physician control. Shi presented the key concepts of a stereo-fluoroscopic image-guided robotic biopsy system, but only simulations were done [1]. Loser developed a prototype robotic needle driver for use in interventional procedures and described experiments using pig organs [2].

2. SYSTEM COMPONENTS & BIOPSY SCENARIO

The system components are shown in Figure 1:
1. mobile CT scanner (Philips Medical Systems)
2. localizer (hybrid Polaris from Northern Digital)
3. "needle driver" robot (PAKY/RCM: Urology Robotics Lab at Johns Hopkins [3])
4. Windows NT based personal computer and software including the user interface

The scenario envisioned for robotic spine biopsy is as follows:
1. The patient is positioned on the table and a series of axial CT scans are obtained
2. The scans are transferred from the operator's workstation to the CT workstation over an Ethernet connection using the DICOM protocol
3. The user interface software allows the physician to select the axial scan of interest and the region to be biopsied (entry location and target point)
4. The entry location for the biopsy is marked on the patient's skin (using the laser lights on the scanner and measuring off the centerline as necessary or by a registration technique that is described in the next section)
5. The robot is manually positioned at the skin entry point (necessary as the robot does not have a translational capability – this feature is currently under development)
6. The robot automatically orients the needle and inserts it to the correct depth
7. A CT scan is obtained to verify the needle position
8. The biopsy sample is taken

Some initial experiments have been done using the setup shown in Figure 2. These experiments verified the basic concept.
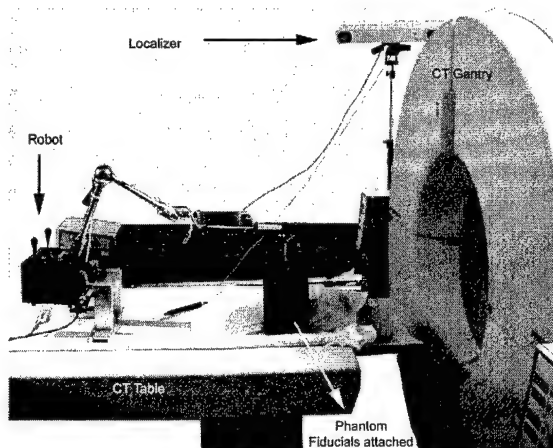
3. USER INTERFACE

The user interface is shown in Figure 3. The screen is divided into two areas: an image display area (the left ¾ of the screen) and a program control area (the right ¼ of the screen).
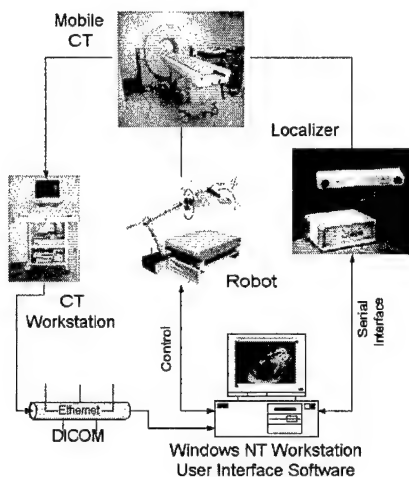
Figure 1: Testbed components

Figure 2: Experimental setup

The program control area has four panels: tracker, image, robot, and registration. The CT images shown were obtained using an interventional phantom (CIRS Inc., Norfolk, Virginia) and the mobile CT. The bright spots above the scans are from a fiducial carrier that was placed into the vertebral body for registration purposes as described below. The user interface software was developed using Visual C++ and the Microsoft Foundation Classes (MFC).
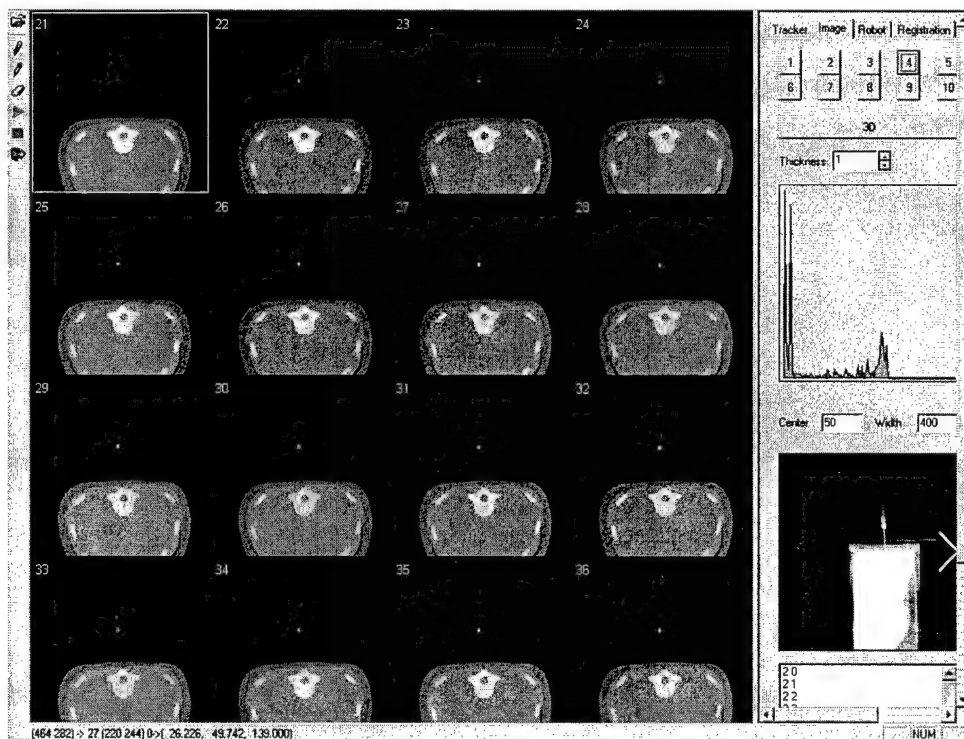
Figure 3: User interface showing initial screen after loading images

The four panels of the program control area are shown in Figure 4. The tracker panel is for the localizer which is capable of tracking up to 3 active and 3 passive tools. The image panel specifies the image display area and a series of axial slices can be specified (1 by 1 to 10 by 10) or an axial/saggital/coronal view as shown in Figure 5. The robot panel allows the

user to control the robot as well as verify the commands to be sent to the robot. Finally, the registration panel is used to start the registration process as well as verify the results.
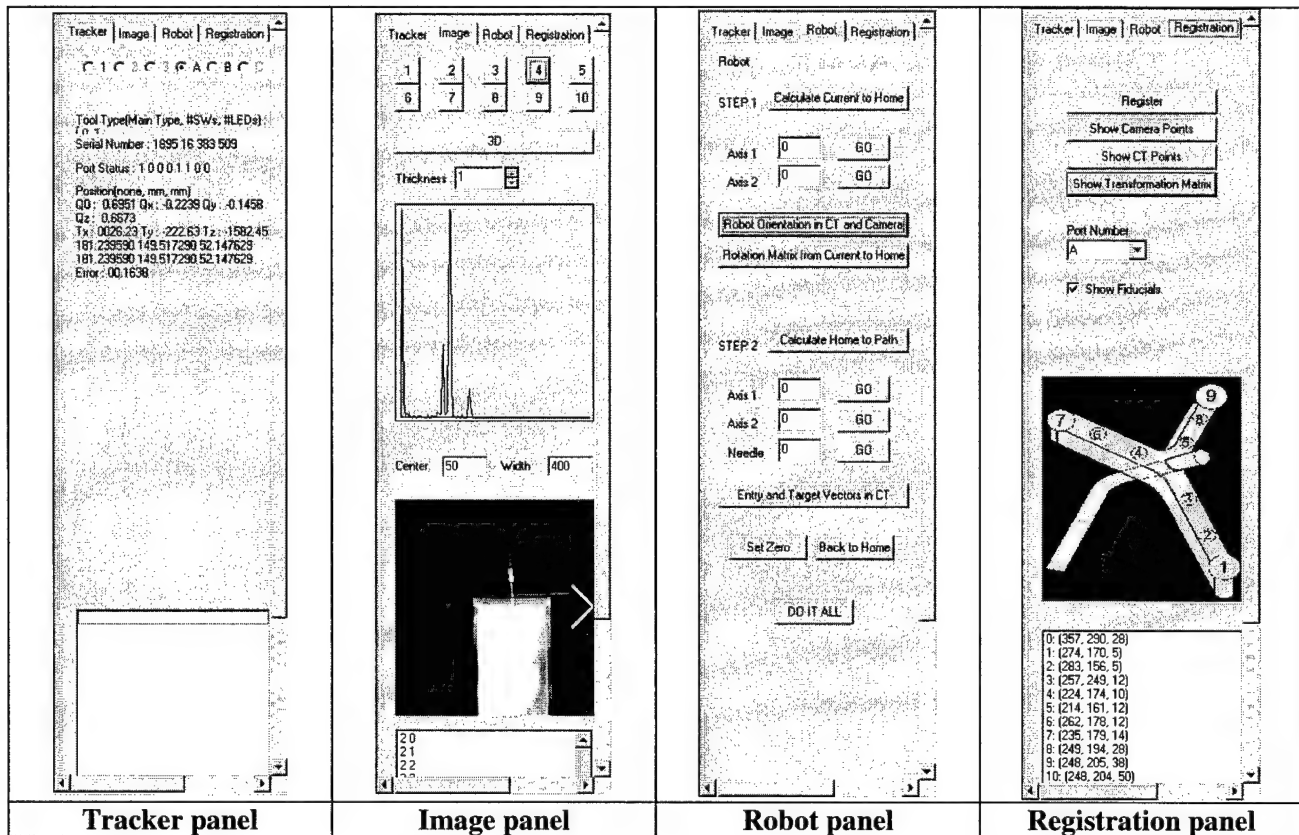
Figure 4: Control panels

As described in the biopsy scenario in Section 2, the user interface allows the physician to select the desired skin entry point and target point as shown in Figure 6. Note that these points do not need to be on the same CT slice (in current practice they typically are so the physician can more easily follow the needle path). Once these points are selected, the software automatically draws a line on all the CT slices involved, indicating the segment of the line coincident with the needle path in a different color. In Figure 6, the biopsy path is drawn in a very light color but extends from CT slice 22 to slice 28.

The registration process proceeds as follows [4, 5]. A fiducial carrier (PassTrax, Traxtal Technologies, Toronto, Canada) consisting of a plastic tracking frame and nine radio-opaque microspheres is rigidly attached to the vertebral body of an interventional phantom (see Figure 7 and Figure 8). The fiducial carrier also holds three retro-reflective spheres whose position can be determined by the localizer. These three spheres give the position and orientation of the fiducial carrier in the localizer coordinate system. The nine microspheres are at known calibrated locations relative to the spheres and so the positions of the microspheres in localizer space can also be determined. The microspheres also show up as bright spots on the CT image whose position in CT coordinates can be automatically determined. Therefore, we know the position of the nine microspheres in both the localizer and CT coordinate systems. These data can be used to determine the transformation matrix between the two coordinate systems. This transformation matrix will be used in the coordinate system transformations described in Section 4.
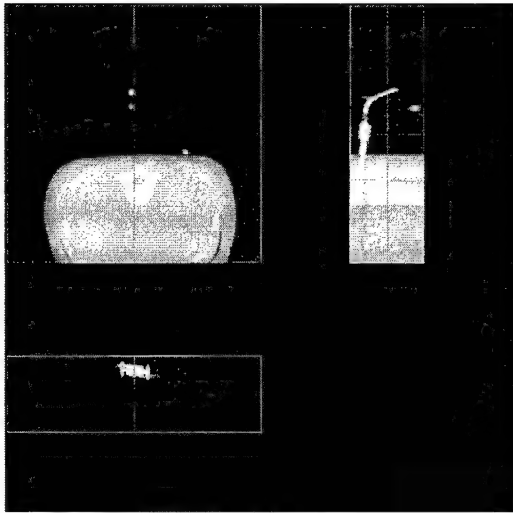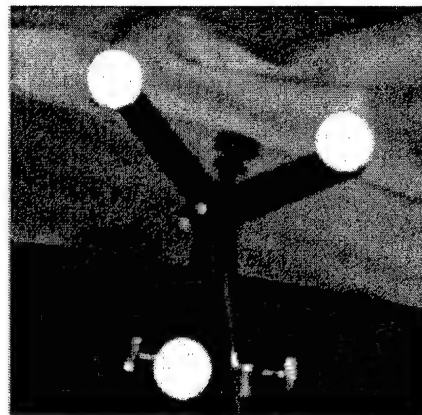
Figure 5: Axial/saggital/coronal view
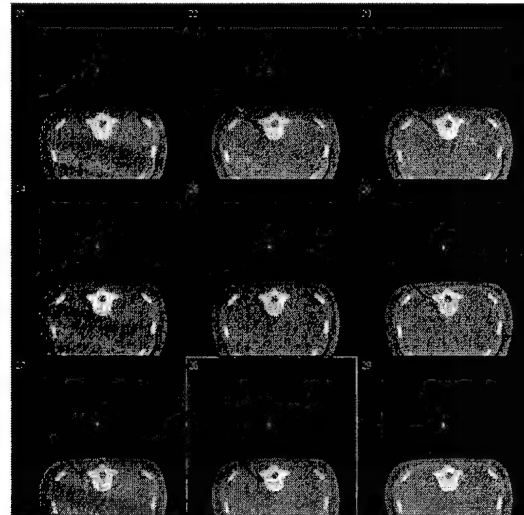
**Figure 6: Path planning
across multiple slices**

**Figure 7: Interventional phantom
with fiducial carrier**

**Figure 8: Close-up of fiducial carrier
showing retro-reflective spheres**

4. COORDINATE SYSTEM TRANSFORMATIONS

Once the physician has indicated the desired biopsy path on the CT images and the registration process has been completed, the next step is to command the robot to orient and drive the needle. This requires us to determine the transformations between the various coordinate systems. To describe the position and orientation of a rigid body in three-dimensional (3-D) space, we attach a coordinate system to the object [6]. We then describe the position and orientation of this coordinate system relative to some other coordinate system (typically called the reference coordinate system).

The coordinate systems we use are shown in Figure 9 and defined as follows:

1. CT coordinate system. The origin is at the top left and on the first slice of a set of slices. The x-axis is from left to right, the y-axis is from top to bottom, and the z-axis is from foot to head (front to back).

2. Localizer coordinate system. This system is defined by the manufacturer and the origin is centered between the lenses. The x-axis is pointing down, the y-axis is to the left as you face the localizer, and the z-axis is directed out the back of the localizer.

3. Tracker coordinate system. This tracker is mounted at a fixed location on the robot and provides the orientation of the last link of the robot. This coordinate system is defined by the vendor through a ROM file which is downloaded to the localizer. The origin is centered on the fiducial point shown. In our implementation, the x-axis is pointing down, the y-axis is to the right, and the z-axis is determined by the right hand rule.

4. Needle coordinate system. This coordinate system is located at the remote center of motion point on the robot. The z-axis is down along the needle, the x-axis is pointed back towards the center of the last link, and the y-axis is defined by the right hand rule.

All of these coordinate systems are used to relate the CT coordinate system to the needle coordinate system. The robot is commanded to move the needle to the desired orientation as outlined in the following steps.

Step 1: Query the localizer to read the orientation of the tracker mounted on the robot. This orientation is given with respect to the localizer coordinate system.

Result: $^{localizer}R_{tracker}$ where R denotes a 3 by 3 rotation matrix. The subscript denotes the object of interest and the superscript denotes the reference coordinate system.

Step 2: Compute the orientation of the needle with respect to the localizer coordinate system. There is a fixed transformation ($^{tracker}R_{actual\_needle}$) from the needle to the tracker that is determined by the geometry.

$$^{localizer}R_{actual\_needle} = {}^{localizer}R_{tracker} \times {}^{tracker}R_{actual\_needle}$$

Step 3: Compute the orientation of the needle with respect to the CT coordinate system.

$$^{CT}R_{actual\_needle} = {}^{CT}R_{localizer} \times {}^{localizer}R_{actual\_needle}$$

where $^{CT}R_{localizer}$ was determined by the registration procedure described in Section 3.

Step 4: Since we know the desired needle orientation in CT space $^{CT}R_{desired\_needle}$ (from the path planning step described in Section 3) we can compute the rotation matrix between the actual needle orientation and the desired needle orientation. This rotation matrix can then be used to command the robot to the desired needle orientation.

$$^{desired\_needle}R_{actual\_needle} = \left[{}^{CT}R_{desired\_needle} \right]^{-1} \times {}^{CT}R_{actual\_needle}$$

5. CONCLUSION

This paper described the concept behind a robotically assisted biopsy testbed. Some details concerning the user interface and coordinate systems employed were also given. The next step is to compare the performance of the robotic biopsy testbed to the current physician directed technique in phantom studies. We have also been working with The Center for Computer Integrated Surgical Systems and Technology at Johns Hopkins and the Surgical Planning Laboratory at Brigham and Women's Hospital to adapt 3D Slicer for the user interface [7]. This system is a first step in developing the precision robotic-assisted systems of the future to aid in interventional procedures.
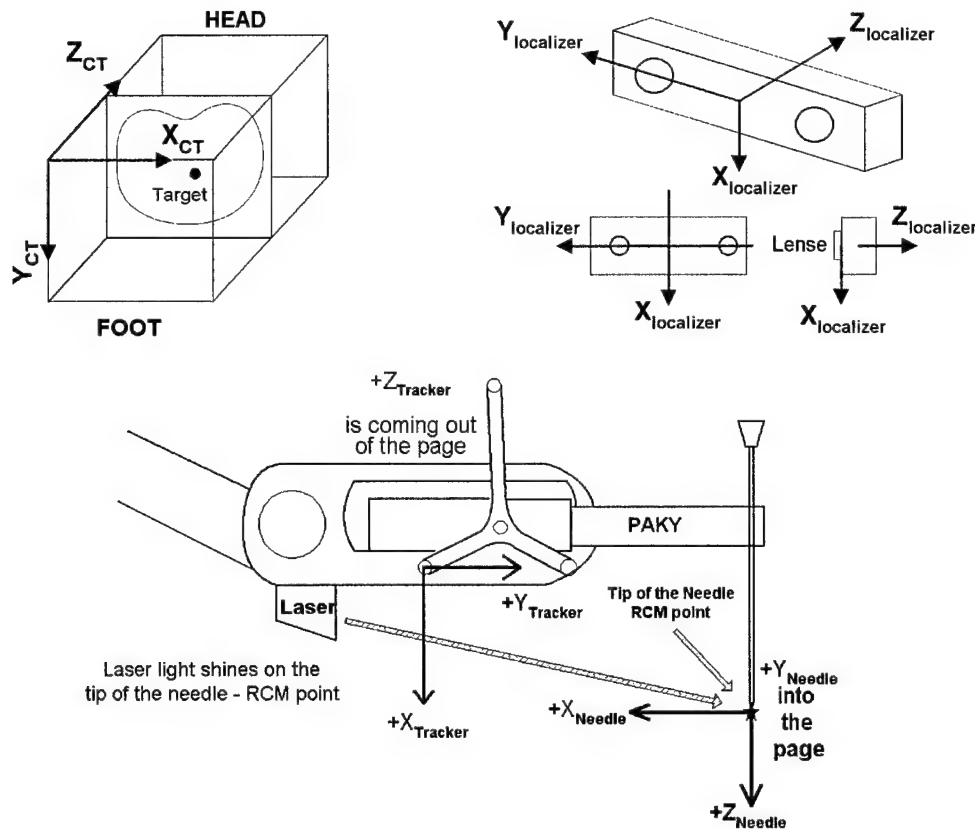
Figure 9: Coordinate systems: CT, localizer, tracker, and needle

ACKNOWLEDGEMENTS

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10.3 Posters

Copies of the three posters produced during this reporting period are reproduced in this section.

10.3.1　　Cleary 2001e: Automatic Registration

Poster is reproduced on the next page. Presented at the CARS conference June 2001 in Berlin, Germany.

Automatic Registration for Percutaneous Vertebral Body Tracking

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PURPOSE

The registration of cross-sectional medical images with patient anatomy is an important problem in image-guided surgery. Current registration methods such as paired-point matching can be tedious and require large incisions. Improved methods of registration for percutaneous spine procedures could potentially improve the accuracy of minimally invasive spine procedures. In this poster, we will describe a combination of hardware and software for the automatic registration of a vertebral body with cross-sectional medical images. The technique is based on a fiducial carrier attached directly to the spinous process and does not require the user to identify anatomical landmarks.

METHODS

The fiducial carrier is a plastic passive tracking frame as shown in Figure 1 (PassTrax-PS, Traxtal Technologies, Toronto, Canada). The frame holds three passive retroreflective spheres which can be automatically tracked by the infrared camera system shown in Figure 2 (hybrid Polaris, Northern Digital, Toronto, Canada). The frame also contains nine radio-opaque microspheres which serve as fiducials for the registration process.

For these tests, the frame was rigidly attached to the spinous process of an abdominal interventional phantom (CIRS, Norfolk, Virginia) using a locking pin as shown in Figures 3 and 4. In a simulated biopsy procedure, the phantom was then placed on a CT table and a series of axial slices were scanned. These axial slices were then registered with the coordinate system of the infrared camera system as described below. This registration enables the operator to track any point on the phantom with a passive pointer and overlay the position of the pointer on the CT scans.

Figure 1: Passive tracking frame (Courtesy of Traxtal Technologies, Inc.)

Figure 2: Hybrid Polaris infrared camera system (Courtesy of Northern Digital, Inc.)

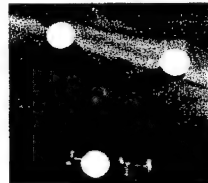Figure 3: Interventional phantom and mounting of tracking frame

Figure 4: Close-up showing carrier and retroreflective spheres

The registration process consists of the following steps: 1) thresholding; 2) connectivity checking; 3) fiducial identification; and 4) transformation matrix computation.

Thresholding

Because the fiducials were designed to be radio-opaque, they show up as bright spots on the CT image. The image is thresholded by removing all pixels with an intensity below 2000 Hounsfield units. The remaining pixels are either part of the fiducials or artifacts. Note that, in clinical practice, artifacts may been seen in patients with metal instrumentation in the spine, which is not an uncommon occurrence.

A three-dimensional (3D) view of the CT data set thresholded to highlight the fiducials is shown in Figure 5. This rendering was done using the commercial visualization software Voxar (Edinburgh).

Figure 5: Three-dimensional rendering thresholded to highlight fiducials

Connectivity Checking

The next step is to determine which pixels are connected to each other and therefore are part of the same object. Since the fiducials are about 1 mm in diameter and the pixel spacing on our mobile CT scanner is typically about 0.50 mm, each fiducial will appear on several pixels. In addition, there is some scattering of the x-ray beam from the CT due to the fiducials, making them appear larger than they actually are. To determine connectivity, we use a standard technique called "labeling". We traverse through the images row by row and slice by slice to build another data set of the same size but with labels used instead of pixel values. Once the connectivity analysis is completed, the centroid of each fiducial can be computed by a weighted average of the pixels contained in it.

Fiducial Identification

At this point, we have a list of fiducials and their positions in CT space. To determine which fiducial in CT space corresponds with what fiducial on the tracker, we use a feature-based identification algorithm called "interpretation trees". Since the location of the fiducials on the tracker is known, the simplest features that we can extract from the tracker are the distance between each pair of fiducials (the fiducial locations are calibrated by the manufacturer and this data is supplied to each user). We then construct a 9 by 9 table that contains these distances. From the points detected in the CT images in the connectivity analysis above, we develop a similar table. For example, if we detected 9 fiducials and 2 artifacts in Steps 1 and 2, the table in CT space would be 11 by 11. We have developed an algorithm to compare these two tables and identify the corresponding fiducials.

Transformation Matrix Computation

From the steps above, we now know the positions of all the fiducials in CT space and the corresponding fiducial on the tracker. We can also compute the positions of the fiducials in camera space by reading the positions of the retroreflective spheres on the fiducial carrier. From this information and the known geometry of the fiducial carrier, we can compute the positions of all the fiducials in camera space. This is a classical problem in the registration literature, and standard techniques such as a least squares fit can be used to solve for the transformation matrix between the two data sets.

RESULTS

The registration algorithm described here was implemented as part of a robotic biopsy test-bed consisting of a mobile CT scanner, a hybrid Polaris camera, and a personal computer. The fiducial carrier was rigidly attached to the spinous process of an interventional phantom. The phantom was scanned and the CT images were transferred to the personal computer. The images could be viewed as either multiple axial slices (Figure 6) or as axial/sagittal/coronal images (Figure 7).
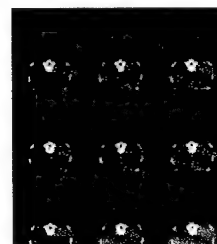

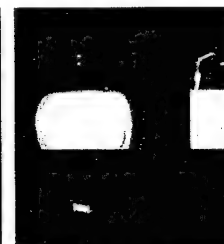Figure 6: Multiple axial slices

Figure 7: Axial/sagittal/coronal images

The registration software was then invoked from this user interface to determine the transformation matrix from the camera system to the CT images. The registration control panel is shown in Figure 8.

To test the accuracy of the registration, the position of a passive probe was tracked by the camera system and overlaid on the CT images. Inspection of the overlay indicated a good correlation. More detailed experiments to quantitatively determine the accuracy of this method are in progress.

Figure 8: Registration control panel

CONCLUSIONS

This paper describes a method for registering cross-sectional medical images with patient anatomy without user input. The method has been implemented in software for a robotic biopsy test-bed and preliminary studies have shown good correlations. These techniques have many applications in image-guided surgery and could open the door to a wider variety of minimally invasive techniques.

ACKNOWLEDGMENTS

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10.3.2   Cleary 2001f: Respiratory Liver Motion Simulator

Poster is reproduced on the next page. Presented at the CARS conference June 2001 in Berlin, Germany.

Respiratory Liver Motion Simulator:
a paradigm for percutaneous liver procedures using magnetic tracking

Kevin Cleary, PhD[1] Sumiyo Onda, BS[1]
Filip Banovac, MD[1,2] Lei Jiang, MS[1]
Elliot Levy, MD[2] David Lindisch, RT[1]
Daigo Tanaka, MA[1] Gabriela Corral[1]

Imaging Science and Information Systems (ISIS) Center
Department of Radiology
Georgetown University, Washington DC

Department of Radiology
Georgetown and Medstar Hospitals
Washington DC

MedStar Health

PURPOSE

To demonstrate a novel system for tracking of internal organ position and motion based on the AURORA™ Magnetic Tracking System connected to a catheter based magnetic fiducial. This is a first step in validation of magnetic tracking as a technology that can be applied clinically in minimally invasive percutaneous liver procedures.

INTRODUCTION

A number of commercially available surgical navigation systems exist. However, these systems can only be used for a limited number of cranial, orthopedic, and maxillofacial procedures as other internal organs are subject to considerable respiratory motion. We present an integrated system that could serve as a basis for extending the navigation to virtually all internal organs.

A system consisting of an AURORA magnetic field generator, a catheter based fiducial, an active magnetic probe, an interventional liver phantom, and a moving platform has been designed and manufactured. This system allows the user to track and display the position of the model liver thus simulating the motion of the liver seen with respiration. It also allows the display of the liver position in real time, serving as a paradigm for percutaneous liver interventions using previously acquired CT images.

SYSTEM COMPONENTS

Physical Model

Torso

A commercially available model torso (Figure 2) has been modified to accommodate a motorized platform placed into its base. In its original form, the torso has 19 removable parts and organs.

Figure 2: Model torso

Liver

A phantom liver model was manufactured (Figure 3). This liver model incorporates several important physical and imaging characteristics. Made from cured silicone rubber VI-SIL 1068 (Rhoda VSI, Troy, NY, USA) and cast into a custom made Instamold (Active Products, Marshall, TX, USA), the liver contains tubular, branching vein models (vena cava and hepatic veins). It also incorporates radio-opaque nodular 1-2 cm tumors. The tumors were made by addition of dilute hypaque radiographic contrast medium to the silicone compound prior to curing.

Figure 3: Liver

Linear platform with servomotor

A linear motion platform (Figure 4) powered by a digitally controlled servomotor (Figure 1,a) (Bearing Engineers, Inc., Aliso Viejo, California, USA) was manufactured to allow the phantom liver mounting onto a radiolucent plexiglass sheet. The liver is mounted onto the plexiglass which is in turn placed on the passive and active linear motion stages (ALM , Westbury, NY, USA) (Figure 1,b)
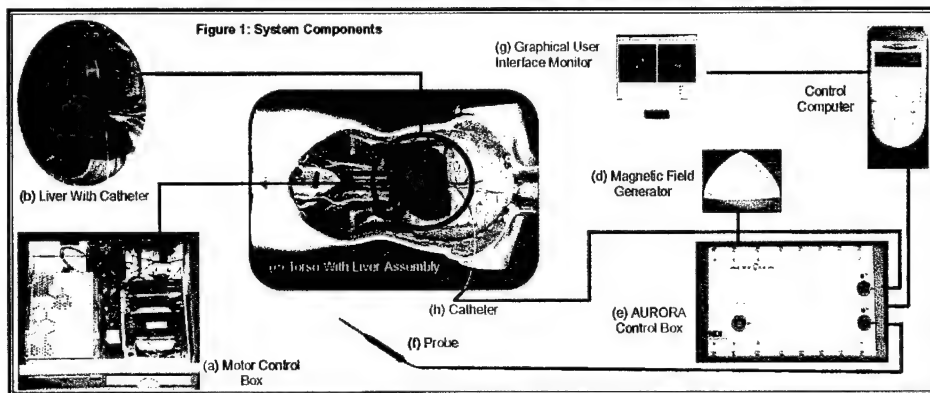
Figure 4: Linear motion platform

Hardware

Tall Paul mounted liver assembly

The components described above are integrated into a demonstration unit consisting of the torso, the servomotor powered linear stage, and a phantom liver model (Figure 1,c).

Figure 1: System Components

(g) Graphical User Interface Monitor
Control Computer
(b) Liver With Catheter
(d) Magnetic Field Generator
(c) Torso With Liver Assembly
(h) Catheter
(e) AURORA Control Box
(f) Probe
(a) Motor Control Box

AURORA™

AURORA magnetic tracking system (Northern Digital, Inc., Ontario, Canada) consists of a magnetic field generator (Figure 1,d), a system control unit (Figure 1,e) and a system interface unit attached to a catheter (Figure 5) with a 0.9mm x 9mm coil embedded in its tip. This system tracks the catheter tip position and orientation with 1-2 mm accuracy (Table 1).
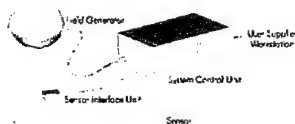

Figure 5: Magnetic tracking system (Courtesy of Northern Digital, Inc.)

	5D Sensor	6D Sensor
Accuracy positional	1-2 mm 3D RMS[1]	1 mm 3D RMS
Accuracy angular	0.5° - 1° RMS[1]	0.5° RMS
Sensor		
Dimensions	0.9 mm dia x 8 mm	Customized
Number of Sensors	1 - 10	1 - 10
Measurement Rate	20 - 60 Hz[2]	20 - 60 Hz[2]
Sensor Interface Unit		
Dimensions	60 mm x 60 mm x 25 mm	
Weight	75 g	
Field Generator		
Dimensions	225 mm x 225 mm x 210mm	
Weight	2 kg	
System Control Unit		
Dimensions	365 mm x 235 mm x 135 mm	
Weight	5 kg	

Table 1 (Courtesy of Northern Digital, Inc.)

Magnetic instrument probe

Designed by Traxtal, Inc. Ontario, Canada, the probe is compatible with the AURORA system which allows the user to display the instrument position and orientation in near real time. (Figure 1,f)

Software

Motor control software

An open code control software ZCC from WorldServo, Rochester, NY, USA) was modified to control the excursion distance, rate and dwell of the mounted liver platform in order to simulate human breathing patterns.

Graphical User Interface

A user friendly Graphical User Interface (Figure 6) was developed allowing the display of previously acquired CT slices of the Tall Paul with its mounted liver. The software can display the axial slices, sagittal reconstructions and oblique slices that are dictated by the position and orientation of the magnetic instrument probe (Figure 1,g)
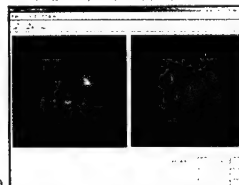
Figure 6: Graphical User Interface

PROCEDURE

1. Tall Paul model torso with an interventional liver phantom mounted on a moving platform is placed in the CT scanner.
2. A catheter containing a small 0.9 mm x 9 mm magnetic coil (Figure 1,h) is wedged in the liver model's hepatic vein.
3. A series of thin 1-2 mm axial slices is obtained from the base of the lungs through the liver while the liver position is held in end-expiration (simulating breath hold technique during CT scanning).
4. Tall Paul model torso with the magnetic fiducial catheter still in place is then taken out of the CT scanner and is brought to an interventional radiology suite.
5. Magnetic field generator (figure 1,d) is enabled and the position of the catheter is determined in "magnetic space"
6. Semiautomatic registration algorithm overlays the "magnetic space" and the "CT image space".
7. Interventional Radiologist uses an active magnetic probe (figure 1,f) to approach the liver as he or she would during percutaneous liver biopsy or percutaneous liver tumor ablation.
8. The monitor displays the cross sectional images of the liver reformatted to the plane parallel to the magnetic probe "instrument view", allowing the radiologist to see the exact projected path of the instrument in real time.
9. The cross sectional plane can be displayed either with the motion platform stopped (performing the procedure during breath hold) or while the liver is moving (performing the procedure in a respiring patient).

CONCLUSIONS

The integrated navigation system for image guided procedures as described here is a paradigm for future applications in minimally invasive radiology and surgery. The system serves as a first step in validation of magnetic tracking technology as it would be applied in assisting physicians to perform minimally invasive procedures on internal organs that move during the respiratory cycle.

This demonstration conveys the use of this system in a liver model; as such it could be applied to help target small liver tumors for biopsy or ablation. In the future it could be applied to percutaneous cholangiography, percutaneous biliary drainage, and portosystemic shunt creation. It is also amenable to modifications that would expand its uses to most intra-abdominal and intrathoracic organs.
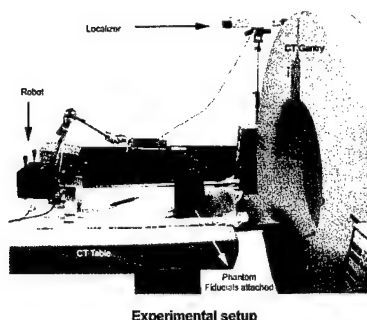
ACKNOWLEDGMENTS

10.3.3   Cleary 2001g: Robot Biopsy Testbed

Poster is reproduced on the next page. Presented the NSF site visit to the Johns Hopkins University Engineering Research Center in January 2002.

CT-Directed Robotic Biopsy Testbed

THE PROBLEM

- Percutaneous (minimally invasive) interventions require accurate needle placement
  - There are limitations to the accuracy that can be obtained from freehand techniques
  - When the physician releases the needle, it can drift or tilt from the desired position
- Percutaneous biopsy can be tedious and time consuming

Experimental setup

Testbed Components

THE SOLUTION

- Develop a robotic assist system that is linked to the CT images to assist the physician in precision placement of the biopsy needle
- System components:
  - mobile CT scanner
  - localizer
  - "needle driver" robot
  - user interface and control software

THE IMPACT

- This is a first step toward demonstrating the potential of robotics to automate percutaneous needle interventions
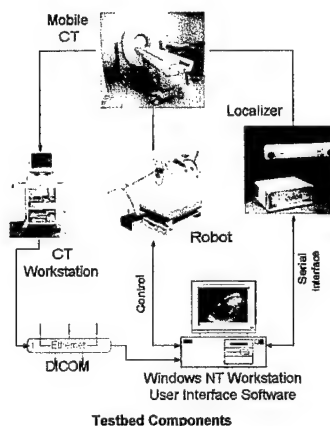
THE FUTURE

- Next step is to integrate new needle driver robot from Urology Robotics Laboratory

- Will integrate 3D Slicer as the user interface

- Plan to test automated system versus residents and physicians at Georgetown

Path planning across multiple slices

PEOPLE INVOLVED

- Georgetown University Medical Center: Kevin Cleary, Filip Banovac

- John Hopkins: Sheng Xu, Gabor Fichtinger, Dan Stoianovici
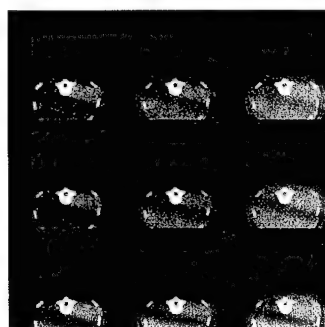
- Traxtal Technologies: Neil Glossop

SUPPORTED BY:

INVENTIONS AND PUBLICATIONS

- Cleary K, Onda S, Banovac F, Lindisch D, Glossop N, Jiang L, Xu S, Patriciu A, Stoianovici D, "CT-directed robotic biopsy testbed: user interface and coordinate transformations," Computer Assisted Radiology and Surgery (CARS) 2001, Elsevier, 171-177.

- Cleary K, Xu S, Fichtinger G, Glossop N, "Automatic registration for percutaneous vertebral body tracking," poster presented at Computer Assisted Radiology and Surgery (CARS), Berlin Germany, June 2001 (also published in the proceedings from Elsevier, page 1141).

10.4 Protocol for Vertebral Body Motion Tracking

Protocol begins on the next page and is 9 pages long.

Number: _____
Date Received _____
Date Reviewed by IRB _____
Approved   Deferred   Disapproved

GEORGETOWN UNIVERSITY MEDICAL CENTER
PROTOCOL FOR CLINICAL STUDY

1. **Title of Project:** Periscopic Spine Surgery: Vertebral Body Motion Tracking

2. **Purpose of Project:** The purpose of this research study is to gather data on vertebral body motion during vertebroplasty using a non-invasive sensor. Vertebroplasty is a minimally invasive technique in which PMMA (polymethylmethacrylate: bone cement) is injected into the vertebral body to strengthen the body and stabilize the spine. The motion of the vertebral body will be measured by attaching a non-invasive sensor to the vertebroplasty trocar. An optical tracking system will be used to determine the position and orientation of this sensor and hence the vertebral body motion. This data will be valuable for developing the next generation of image-guided techniques that require the tracking of vertebral body motion.

3. **Principal Investigator:** Vance Watson, MD
    Director of Neurointerventional Radiology
    Department of Radiology
    3800 Reservoir Road NW
    CCC Ground Floor
    Washington DC 20007
    Telephone Number: 202-784-3420

4. **Location of Study:** Angiography Suites, Georgetown University Medical Center. The address is the same as in item 3. The site director is Dr. Watson.

5. **Names and roles of co-investigators:**
    Kevin Cleary, PhD, ISIS Center, Radiology Department, 202-687-8253.
    Sumiyo Onda, BS, ISIS Center, Radiology Department, 202-687-2902.
    David Lindisch, RT, ISIS Center, Radiology Department, 202-687-0369

Dr. Cleary is the principal investigator of the Periscopic Spine Surgery project, which is funded by the U.S. Army Medical Research and Materiel Command. This research study is a natural outgrowth of our ongoing work on this project in developing new techniques for image-guided

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procedures. Sumiyo Onda and David Lindisch are research associates who will assist with the data gathering and operation of the equipment.

6. **Study information** required for Georgetown and Army protocols is listed here.

 Estimated start date: February 2001

 Estimated completion date: July 2001

 Estimated project duration: 6 months

 Estimated total number of subjects: 10

 Age range of subjects: subjects must be greater than 18 years of age.

 Inclusion/exclusion: None – all patients undergoing vertebroplasty are eligible.

 Source of subjects: patients will be recruited from within Georgetown University Hospital and affiliated outpatient practices and the existing practice of Dr. Vance Watson.

7. **Grant support for project:** U.S. Army Medical Research and Materiel Command, grant DAMD17-99-1-9022 (Periscopic Spine Surgery). The protocol and consent form will be reviewed by the Human Subjects Research Review Board (HSRRB) of the U.S. Army after approval at Georgetown.

 There is no pharmaceutical company support for this project.

8. **Brief historical background of the project with reference to the investigator's personal experience and to pertinent medical literature.**

The overall goal of the Periscopic Spine Surgery project is to advance the state of the art in image-guided and minimally invasive spine procedures. To this end, Dr. Cleary and Dr. Watson have been developing a number of innovations at Georgetown over the past two years, including the use of a mobile CT scanner in the neurointerventional suite and the development of a "needle driver" robot for precision placement of needles in the spine. In the further development of these and other techniques, precise data on vertebral body motion is essential.

During vertebroplasty, as is routinely performed at Georgetown, a rigid trocar is placed in the vertebral body and PMMA (bone cement) is injected through this trocar. By attaching a non-invasive sensor to this trocar, we can gather data on vertebral body motion safely and easily. Not only will these data be valuable to our research group, but we also plan to publish the data since we feel it will be of interest to other researchers in the scientific community.

Previous studies by Neil Glossop, PhD, have shown that breathing alone can account for 1-2 mm of displacement in the lumbar spine during spine surgery[1]. While the study by Glossop examined

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[1]Glossop, N., HU, R, and Randle, J., "Assessment of vertebral body motion during spine surgery". *Spine* **22**, 903-9

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vertebral body motion during open spine surgery, our study will provide similar data for a percutaneous (minimally invasive) procedure. Dr. Glossop has served as a consultant on the Periscopic Spine Surgery project, and he is an expert in technology development for minimally invasive spine procedures. He is available as required to advise on the study proposed here.

9.   Plan of study.

a. Overview and Description

The study will be conducted in the angiography suites at Georgetown University. The vertebroplasty procedure will follow current clinical practice with the addition of a non-invasive sensor that will be attached to the vertebral body trocar to record its motion. Dr. Watson's instructions to vertebroplasty patients are attached as Appendix A.

Photographs showing one of the angiography suites, fluoroscopy equipment, and a typical vertebroplasty procedure as performed by Dr. Watson are presented in Figure 1 below.
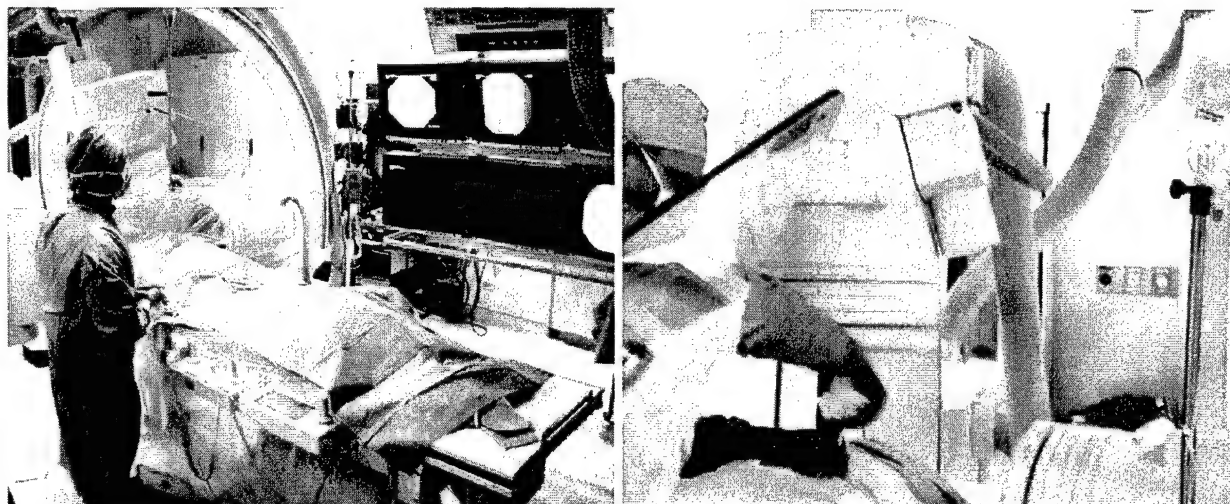

Figure 1: Angiography suite and fluoroscopy equipment at Georgetown (left),
positioning of vertebroplasty trocar in vertebral body (right).
Patient is on table beneath sheets.

The equipment layout for tracking vertebral body motion is shown in Figure 2. The additional equipment introduced for this study consists of: A) the non-invasive sensor; B) the optical tracking system; and C) a personal computer for data collection.

(1997)

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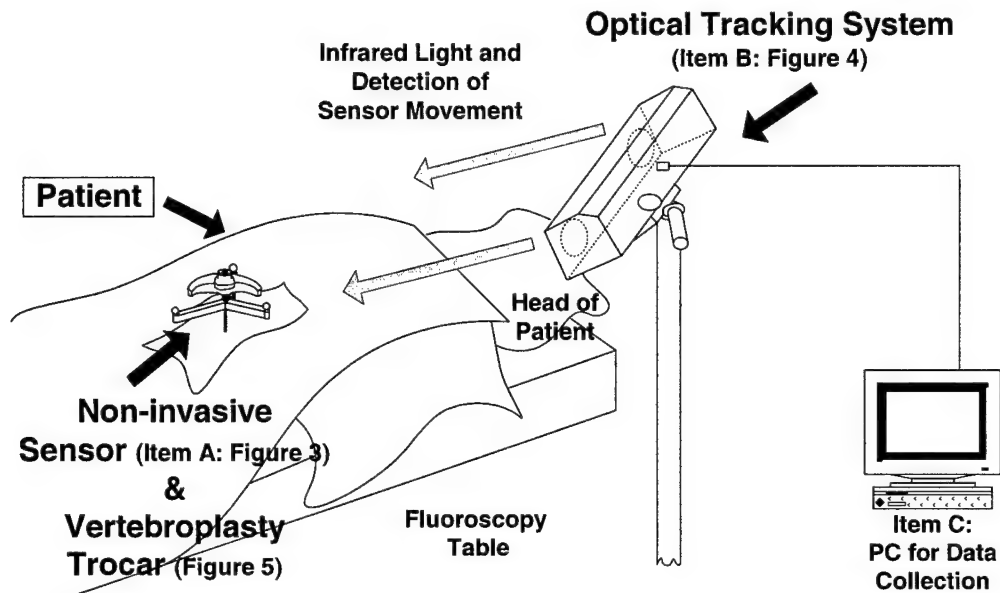Expiration date:

Figure 2: Equipment layout

The non-invasive sensor is shown in Figure 3 and the optical tracking system is shown in Figure 4. The sensor is approximately 50 by 50 mm across and 25 mm high (about 2 by 2 by 1 inch), weighs less than 0.1 kg (about 2 ounces), and contains three reflective spheres arranged in a fixed, known pattern. The sensor is a standard product of Traxtal Technologies, Inc., a company that makes products that can be used in image-guided surgery systems. The sensor is designed to work with the optical tracking system described next.

The optical tracking system emits infrared light that is reflected by these spheres. These reflections are then detected by the optical tracking system and used to determine the position and orientation of the sensor. Since the sensor will be rigidly attached to the vertebroplasty trocar (as described next), the relative position and orientation of the sensor can be used to determine the relative position and orientation of the vertebral body.

Figure 3: Non-invasive sensor	Figure 4: Optical tracking system
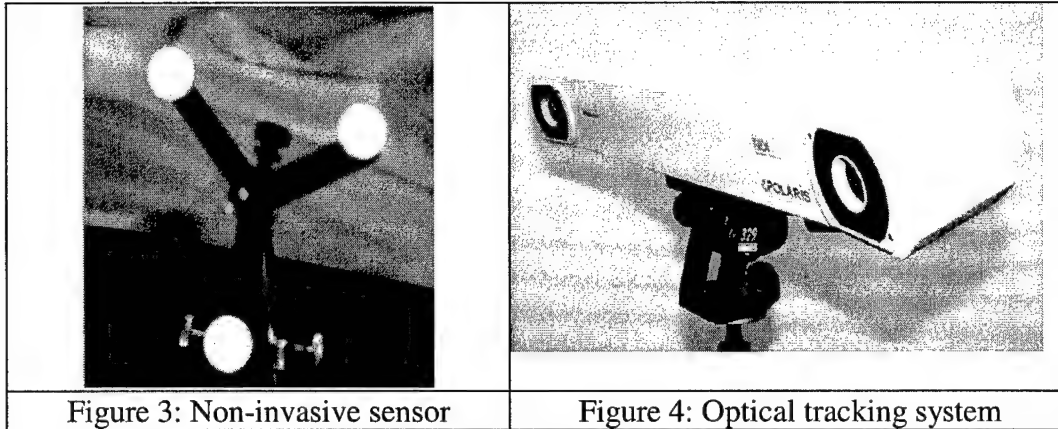
The non-invasive sensor will be sterilized and attached to the vertebroplasty trocar (Figure 5) as shown in Figure 6. The sensor has a mounting hole in the middle of it through which the trocar can be passed. The sensor will then be secured to the trocar by tightening a thumb screw in the side of the sensor. The vertebroplasty trocar and sensor will now move as one unit. Hence, when the trocar is rigidly placed in the vertebral body, recording the relative motion of the sensor is the same as recording the relative motion of the vertebral body. The sensor will not interfere with the procedure nor will it introduce new risk.

Figure 5: Vertebroplasty trocar	Figure 6. Sensor attached to trocar
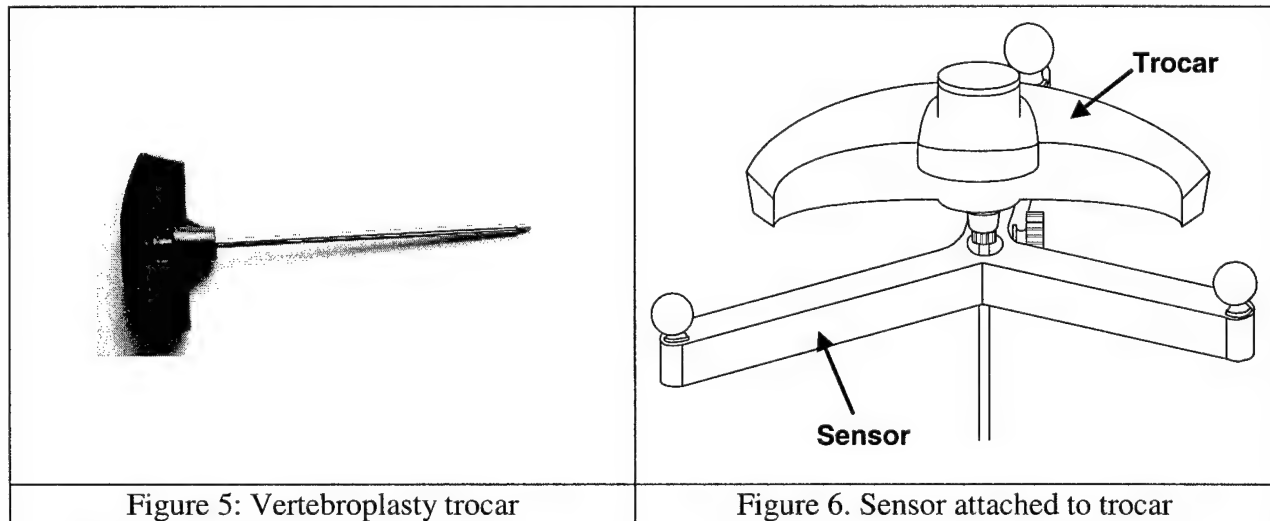
b. Step-by-Step Instructions

1. Informed consent will be obtained from all study participants prior to the start of the vertebroplasty procedure.

2. The non-invasive sensor will be sterilized (see Appendix B) prior to the procedure and strict sterile technique will be observed.

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3. The patient will be positioned prone on the interventional table in the standard manner.

4. The optical tracking system and the personal computer will be placed in the interventional suite so as to maintain a clear line of sight from the optical tracking system to the vertebral body.

5. The vertebroplasty case will proceed in the standard manner. When Dr. Watson is ready to insert the trocar into the vertebral body, he will first attach the sterilized sensor as shown in Figure 6.

6. Once the trocar is inserted into the vertebral body, the position and orientation of the passive tracker will be recorded using the optical tracking system and personal computer.

7. When the case is complete, data recording will stop and the equipment will be removed.

c. Justification as to the Number of Cases Required

This feasibility study is intended to gather data on vertebral body motion during an interventional procedure. Since this data does not currently exist, it is not possible to do a power calculation to estimate sample size. However, based on the previous study by Gossip as cited on page 2 on lumbar spine motion during open surgery, we believe that 10 patients will be sufficient to gather the basic data needed. Once this data is gathered, an estimate of the sample size required for statistical significance can be made.

d. Data Analysis Plan

The data gathered consists of the position and orientation of the passive tracker. For each case, it is anticipated that this data will be obtained at a sample rate of 5 Hz for a period of approximately 5 minutes during the procedures. This will provide 1500 data points (5 samples/second times 60 seconds/minute times 5 minutes). The data points will be stored in an Excel spreadsheet and simple descriptive statistics will be used to analyze the data. This includes the mean and standard deviation. The data will also be plotted to look for trends including the periodic correspondence to respiratory motion (typically about 15 cycles per minute).

10.   Discuss any unusual procedures.

No unusual procedures are planned.

11.   Indicate what you consider to be the risks to the patient and indicate the precautions to be taken to minimize or eliminate these risks.

The risks and discomforts are the same as the usual risks and discomforts associated with vertebroplasty. No additional risks are anticipated. The non-invasive sensor is a commercial product that will be sterilized following the manufacturer's recommendations (given in Appendix B).

12.   Anticipated benefits to subjects

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There is no direct benefit to any individual patient for participating in the study. The data gathered will be useful for researchers developing new image-guided techniques and may prove beneficial to future patients undergoing minimally invasive spine procedures.

13.   Informed consent process

Informed consent will be obtained for all patients participating in the study using the consent form approved by the Institutional Review Board at Georgetown University and the U.S. Army Human Subjects Research Review Board. Before the procedure is carried out, a member of the medical staff will explain the procedure including the risks and benefits and allow the patient to review the consent form as well as answer any questions. The patient will be offered a copy of the consent form. A focused history and physical exam will be included as part of the process. The IRB consent form will be stored in the Interventional Radiology Department in a locked storage container.

14.   Reporting of serious and unexpected adverse events

Serious and unexpected adverse experiences will be immediately reported by telephone to the USAMRMC Deputy Chief of Staff for Regulatory Compliance and Quality [(301) 619-2165, during non-duty hours call (301) 619-2165 and send information by Fax to (301) 619-7803]. A written report will follow the initial telephone call within three working days and will be addressed to: U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ-HR, 504 Scott Street, Fort Detrick, MD, 21702-5012.

15.   Disposition of Data

Research data and related records for this project will be stored at the hospital in the office of our research associate, David Lindisch, RT. This is a private locked office and only study personnel are allowed access to this office. The data will also be stored on a Windows NT personal computer in this office. Access to this computer is password protected. The data will be stored for up to two years after the closure of the study.

Since this computer is connected to the hospital network (which in turn provides Internet connectivity) in order to access the hospital database, steps will be taken to minimize the possibility of external computer attacks. The personal firewall product, BlackICE defender from Network ICE (www.netice.com), will be used to safeguard against computer attacks. This product has been highly recommended by security experts and one of the co-investigators has used this product with great success for the last year.

16.   Modification of the Protocol

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Any modifications to the protocol will be first reviewed and approved by the Georgetown Institutional Review Board (IRB) and then the Army Human Subjects Research Review Board (HSRRB) before implementation. The nature of the modification will determine the type and level of the review.

17.   Describe any special equipment that will be used for this research project.

Special equipment planned for this project is the passive tracker and optical tracking system as described in the Section 9, the Plan of Study. These devices are available commercially and have been used in other medical research applications.

18.   Will any additional care be needed for patients admitted for this project?

No additional care will be required.

19.   Indicate any proposed compensation for participation in cash or in kind.

No compensation or other payments will be made.

20.   Responsibilities of Principal Investigator to the Surgeon General

The material below is clause 13.01 from the U.S. Army Human Subjects Protection Division and is incorporated here for reference. The principal investigator is responsible to:

To promptly report changes or unanticipated problems in a research activity. Normally, changes may not be initiated without TSG approval, except where necessary to eliminate apparent immediate hazards to the human subject or others.

To immediately report by telephone (DSN 343-2165 or 301-619-2165; during non-duty hours call DSN 343-2165 and send information by facsimile to DSN 343-7803 or 301-619-7803) serious or unexpected adverse experiences which occurs to the human subject or others.

To promptly report any change of investigators.

To prepare, at a minimum, an annual progress report or final report in accordance with Title 21, Code of Federal Regulations, Part 312.33.

To immediately report to HSPD knowledge of a pending compliance investigation by the Food and Drug Administration (FDA) or other outside governmental agency concerning clinical investigation or research.

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Signature Page

I certify that the information furnished concerning the procedures to be taken for the protection of human subjects is correct. I will seek and obtain prior approval for any substantive modification in the protocol and will report promptly any unexpected otherwise significant adverse effects encountered in the course of this study.

I certify that all individuals named as consultants or co-investigators have agreed to participate in this study.

1. _____ Date _____

    Vance Watson, M.D.
    Principal Investigator

2. Department chairman:

    Approved _____ Disapproved _____ Date _____

    _____

    Michael Pentecost, M.D.
    Chairman, Department of Radiology

3. Institutional Review Board:

    Approved _____ Disapproved _____ Date _____

    _____

    Chairman, Institutional Review Board

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10.5 FDA Investigational Device Exemption (IDE) Application

Application begins on the next page and is 20 pages long.

Robotically Assisted Spinal Needle Procedures

FDA IDE Application

Submitted To:
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Submitted By:
Kevin Cleary, PhD
Imaging Science and Information Systems (ISIS) Center
Department of Radiology
Georgetown University Medical Center
2115 Wisconsin Avenue
Suite 603
Washington, DC 20007
Phone: (202) 687-8253
Pager: (202) 901-2033
Fax: (202) 784-3479
Email: cleary@georgetown.edu

December 2001

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Appendices

Appendix 1: IRB Documents
>   Appendix 1.1: Protocol
>   Appendix 1.2: Consent
>   Appendix 1.3: Institutional Review Board Approval Letter from Georgetown
>   Appendix 1.4: Human Subjects Board Contractual Approval from Army

Appendix 2: Publications
>   Appendix 2.1: Robotically Assisted Perispinal Nerve and Facet Blocks: A
>   Cadaveric Study (Cleary et al.: unpublished document)
>   Appendix 2.2: Cadeddu, Stoianovici et al. 1998: Stereotactic Mechanical
>   Percutaneous Renal Access
>   Appendix 2.3: Stoianovici, Whitcomb et al. 1998: A Modular Surgical Robotic
>   System for Image Guided Percutaneous Procedures
>   Appendix 2.4: Cleary, Stoianovici et al. 2000: Robotics for Percutaneous Spinal
>   Procedures: Initial Report

Appendix 3: Agreement Letter and Curriculum Vitae
>   Appendix 3.1: Signed Agreement Letter from Vance Watson, MD
>   Appendix 3.2: Curriculum Vitae for Vance Watson, MD

Appendix 4: Case Report and Other Forms
- Case Log
- Form 1: Inclusion/Exclusion Criteria
- Form 2: Demographics
- Form 3: Case Report Form
- Form 4: Procedure
- Form 5: Telephone Questionnaire
- Adverse Events

1 Introduction

This IDE application is to use a joystick controlled robot to precisely place needles in the perispinal region under the direct guidance of a physician. The clinical procedure is for nerve and facet blocks for pain relief. This application is being submitted by Kevin Cleary, PhD, Department of Radiology, Georgetown University Medical Center. The clinical protocol described here has been approved by the Georgetown University IRB and the Human Subjects Board of the Army Medical Command. The physician for this study is Vance Watson, MD, an interventional neuroradiologist at Georgetown.

This IDE application was written following the guidelines in HHS Publication FDA 96-4159, Investigational Device Exemptions Manual, June 1996 (available on the web at http://www.fda.gov/cdrh/manual/idemanul.html). The FDA CDRH web site "Device Advice" was also consulted, in particular the full text Device Advice IDE at http://www.fda.gov/cdrh/devadvice/ide/print/ideall.pdf.

This application is based on a previous application that was submitted in June 2001 and then administratively withdrawn by Dr. Cleary, following the advice of the FDA. Since then, a cadaver study has been completed and the application has been extensively revised and strengthened. This revised application incorporates the comments and suggestions from the FDA from the previous application. This revised application also includes comments and suggestions made by FDA reviewers Yung Pak and Binita Ashar, MD, during a conference call with Dr. Cleary and Dr. Watson on November 19, 2001.

Following the outline suggested in Section 2, Subpart B of the IDE manual, the following information is included in this IDE application:
- Name and address of sponsor-investigator (Section 2)
- A complete report of prior investigations (Section 3)
- An investigational plan (Section 4)
- Description of manufacturing process (Section 5)
- Investigator agreement and names and addresses (Section 6)
- Certification that all investigators have signed the agreement (Section 7)
- Names and addresses of all IRBs (Section 8)
- Name and address of any institution where a part of the investigation may be conducted (Section 9)
- Amount charged for the device (Section 10)
- Claim for categorical exclusion (Section 11)
- Copies of all labeling (Section 12)
- Copies of all informed consent forms (included in Appendix 1 along with the protocol)
- Other relevant information (copies of publications in Appendix 2; signed agreement and curriculum vitae in Appendix 3; case report forms in Appendix 4)

2 Name and Address of Sponsor-Investigator

Kevin Cleary, PhD, is the sponsor-investigator for this project. Dr. Cleary is a research associate professor at Georgetown University Medical Center in the Department of Radiology. He is the principal investigator for the "Periscopic Spine Surgery" project, an Army funded research project to advance the state of the art in image-guided and minimally invasive procedures. The robotic device described in this study was developed under this funding.

The address for Dr. Cleary is:

Kevin Cleary, PhD
Research Associate Professor
Imaging Science and Information Systems (ISIS) Center
Department of Radiology
Georgetown University Medical Center
2115 Wisconsin Avenue, Suite 603
Washington, DC, 20007
Phone: (202) 687-8253
Pager: (202) 901-2033
Fax: (202) 784-3479
Email: cleary@georgetown.edu

3 Report of Prior Investigations

Following the guidelines of Section 812.27 of the Code of Federal Regulations (21 CFR 812), this section includes references to all prior clinical, animal, and laboratory testing of the device.

3.1 Cadaver Study

A cadaver study to evaluate the feasibility of using the device to place a 22-gauge needle for perispinal nerve and facet blocks was conducted at Georgetown University on September 1, 2001. The study was supervised by Dr. Cleary (the investigator-sponsor) and the physician operating the robot was Vance Watson, MD (the clinical investigator).

A full report is attached as Appendix 2.1. The abstract is reproduced here. This study demonstrated the effectiveness of the device.

> **PURPOSE:** To evaluate the feasibility of using a joystick controlled robotic needle driver to place a 22-gauge needle for perispinal nerve and facet blocks.
>
> **MATERIALS AND METHODS:** Bi-plane fluoroscopy and a robotic needle driver were used to place 12 needles into the lumbar perispinal region of a 98 year-old female embalmed cadaver. Small metal BB nipple markers 1 mm in diameter were percutaneously inserted to serve as targets. Six needles were then placed near the nerve root and six needles were placed near the facet root. Anterior-posterior and

lateral radiographs were obtained after each placement to assess the accuracy of placement.

RESULTS: All needles were placed within 3 mm of the target BB. The average placement accuracy was 1.44 mm and the standard deviation was 0.66 mm.

CONCLUSION: A robotic needle driver can be used to accurately place needles in the nerve and facet regions. Clinical studies are required to investigate the advantages and disadvantages of this system for interventional needle procedures.

3.2 Previous Work at Johns Hopkins and Device History

The robotic device was originally developed in the Urology Robotics Department at The Johns Hopkins Medical Institutions to assist in percutaneous placement of a needle in the kidney (Cadeddu, Stoianovici et al. 1998)[1]. As noted in the abstract in this paper, *in vitro* experiments to test needle placement accuracy were conducted using a porcine kidney suspended in agarose gel. Seven copper balls 3 to 12.5 mm in diameter were placed in the collecting system as targets, and successful access was confirmed by electrical contact with the ball. The device was then used clinically in nine patients. No perioperative complications attributable to needle access occurred. A copy of this paper is attached as Appendix 2.2. More details on the robot design and a discussion of the safety issues can be found in (Stoianovici, Whitcomb et al. 1998), a copy of which is attached as Appendix 2.3.

Since this initial work, the basic concept and components of the device have remained the same, while the Hopkins group has worked to refine the system. In the summer of 1999, Dr. Cleary contacted the Hopkins group to suggest that the robotic device could be applied to percutaneous procedures in the spine. A subcontract was issued to Johns Hopkins to construct another robot for Georgetown use. This robot has been constructed and cadaver tests have been completed as detailed in the previous section (Section 3.1). The rationale for the use of robotics in the spine is discussed in a paper by Dr. Cleary and colleagues (Cleary, Stoianovici et al. 2000). A copy of this paper is attached as Appendix 2.4.

4 Investigational Plan

Following the guidelines of Section 812.25, the investigational plan presented here includes the following items (or references to where this material may be found):
- purpose
- protocol
- risk analysis
- description of the device
- monitoring procedures

---

[1] References are given in Section 14 and copies of all papers referenced are in Appendix 2.

4.1 Purpose

This device is a joystick controlled "needle driver" robot that is intended to assist the physician in precision placement of needles during minimally invasive interventions. The objective of this investigation is to demonstrate that a physician controlled robotic needle driver is equivalent in safety and effectiveness to the standard manual technique for needle placement in nerve and facet blocks in the perispinal region. We believe this device may increase the accuracy and efficiency by which these instruments are placed and manipulated, which may lead to better patient outcomes. This study is planned to run from January 2002 until July 2002.

4.1.1 Protocol

The protocol is attached as Appendix 1.1. The Georgetown IRB and the Army Human Subjects Board have approved this protocol. Since our original IDE submission in June 2001 (which was administratively withdrawn) several sections of the protocol have been improved and clarified, based in part on our discussions with the FDA. These modifications are described here in the remainder of Section 4.2. Almost all of these modifications were faxed to the FDA and discussed during our November 19 conference call.
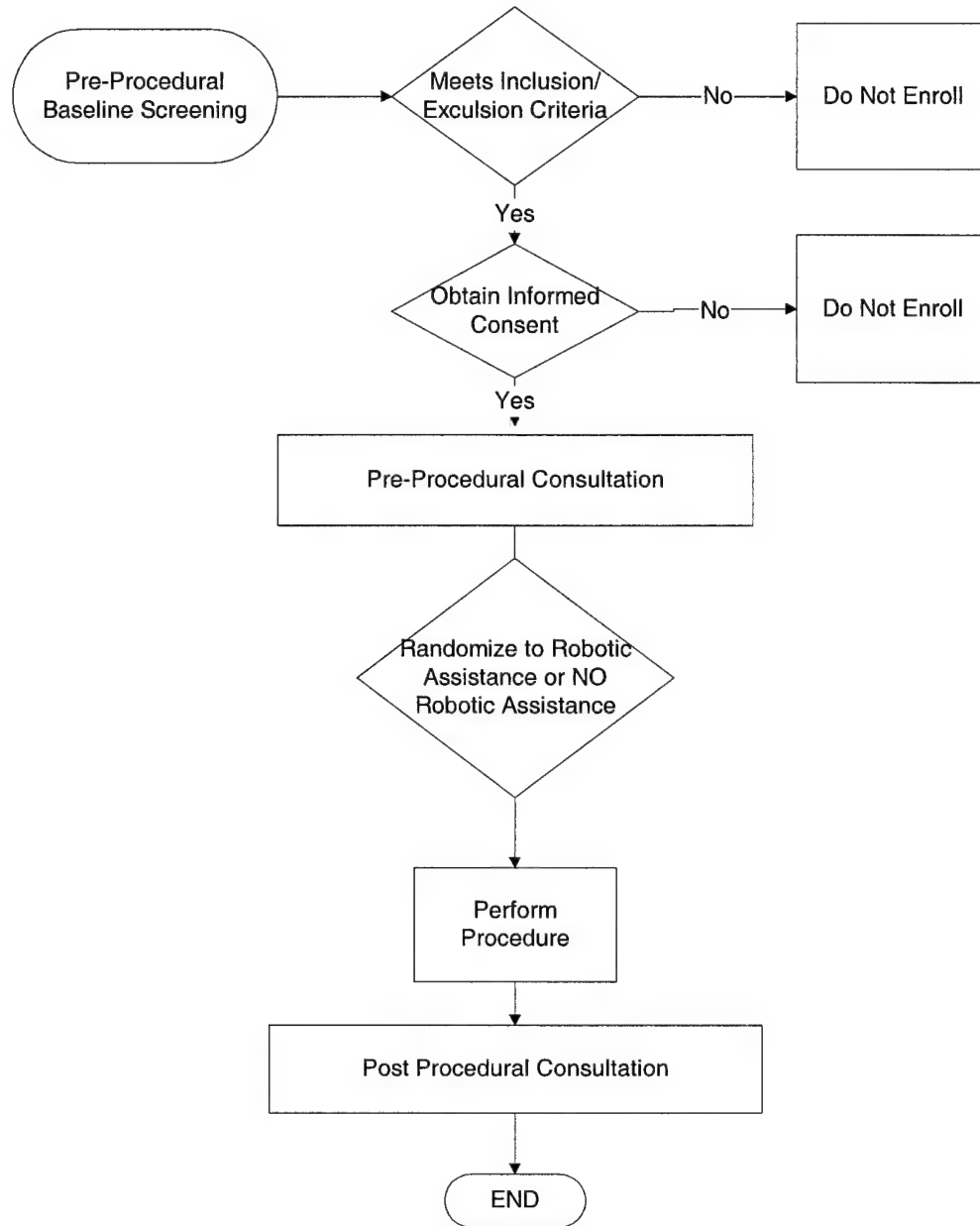
4.1.2 Study Design

This is a single center randomized feasibility study to demonstrate that a joystick controlled needle driver robot is equivalent in safety and effectiveness to the current manual technique for needle placement in nerve and facet blocks in the perispinal region. The study design is shown in Figure 1. We have elected to include 100 patients (50 in each investigational group) to enable us to gather sufficient data for a meaningful statistical comparison between the two groups. We regularly perform approximately 20 blocks a week so recruitment problems are not anticipated. After the first 20 patients (the pilot study) the results will be documented and reviewed by a Data Monitoring and Safety Review Board as stipulated in Section 9c on page 8 of the Protocol (Appendix 1.1).

Once patients meet the inclusion criteria, have given informed consent, and undergone a pre-procedural consultation, they will be randomized to one of two groups: *with robotic assistance* or *no robotic assistance*. The study was intentionally designed in this manner so that the randomization assignment is not made until just before the treatment which should minimize bias.

The randomization scheme will be based on drawing an envelope from a box. The envelope will be non-transparent and sealed with a piece of paper with either the words *with robotic assistance* or *no robotic assistance*. For the pilot study (the first 20 patients), 10 envelopes of each type will be prepared and placed in a box. For the following 80 patients, 40 envelopes of each type will be used. While more complicated

randomization schemes were considered[2], it was felt that they were not necessary for this feasibility study.

Figure 1: Study Design

4.1.3 Description of the Procedure

The procedure follows standard clinical practice. For both nerve and facet blocks, a consultation is done immediately prior to the procedure. This consists of: 1) a medical history; 2) a physical examination including neurological evaluation; and 3) a review of

_____

[2] See, for example, "Clinical Trials: Design, Conduct, and Analysis" by Meinert, Oxford University Press, 1986.

pertinent medical images such as plain films, CT, and/or MRI. The patient's pre-procedure pain is noted by asking the patient to rate their pain on a scale of 1 to 10. If the patient meets the inclusion criteria, informed consent will be obtained and the patient will then be randomized to *with robotic assistance* or *without robotic assistance*.

The patient is then brought into the procedure room and positioned on the table in the prone position. The procedure is done in a neuroangiography suite with biplane fluoroscopy. If robotic assistance is to be used, the robotic system will be secured to the table before the patient is positioned. The robotic system incorporates a hinged mount that can be easily opened and closed to allow the patient to be positioned on the table.

The injection site is then localized using fluoroscopic guidance. To serve as a reference point for later accuracy analysis, the target anatomy will be noted on A/P and lateral fluoroscopy by an arrow overlaid on the image. This feature is part of the biplane fluoroscopy system and these images will be saved in digital format.

Local anesthesia is given by injecting 1% Xylocaine. Sedation is not used. A 22 gauge 3½ or 5¼ inch needle is then placed and advanced to the target area using fluoroscopic guidance. If the robotic system is being used, the robot will be used to place and advance the needle under the joystick control of the physician. If the robotic system is not being used, the current manual technique will be employed. Radio-opaque non-ionic contrast dye (approximately 0.5 cc) may be injected during nerve blocks to visualize the nerve root.

If the robotic system fails in any way (such as the robot not responding to joystick movements or the robotic system shutting down for any reason), the procedure will be converted to a manual procedure. In this case, the robotic system can easily be moved out of the way and the procedure continued in the standard manner. This patient will then be excluded from the clinical trial.

When the needle is at the target location, the injection is done. The robot is not used for this part of the procedure and all injections will be done using the current manual technique. For nerve blocks, 1.5 cc total volume containing 0.5 cc of 10 mg Kenalog and 1.0 cc of 0.25% Bipuvacaine is injected. For facet blocks, 0.75 cc total volume containing 0.25 cc of 10 mg Kenalog and 0.5 cc of 0.25% Bipuvacaine is injected. Both A/P and lateral fluoroscopy images indicating the needle position at the injection site will be saved. The procedure is then complete. The patient is returned to a waiting room. After 10-15 minutes, the post procedural consultation is done, which includes the patient's assessment of their current pain level.

4.1.4 Indications and Inclusion Criteria

The primary indication for nerve or facet blocks is low back pain and/or radiculopathy. The duration of time from initial back pain to undergoing the procedure may vary widely (roughly from 2 weeks or 6 months) depending on the level of pain and physical presentation of the patient. Nerve and facet blocks are considered conservative therapy since they are minimally invasive and done on an outpatient basis (as opposed to open

surgical back procedures). The only test done prior to the procedure is a physical exam including a neurological exam. The patient may also have imaging studies (plain film, CT, and/or MRI). The physician must be able to verify the patient's pain before proceeding with a nerve or facet block.

The inclusion criteria are:
- The patient is 18 years of age or older
- The patient is capable of giving informed consent
- The patient has a confirmed diagnosis of spinal pain based on a neurological exam with pain distribution consistent with dermatomal or facet anatomy

4.1.5 Exclusion Criteria

The exclusion criteria are:
- The patient is under the age of 18
- The patient is not capable of giving informed consent
- The patient is pregnant as determined by laboratory test or clinical history
- The patient is participating in another research study involving another investigational device, procedure or drug
- The patient has coagulopathy, systemic infection, infection at the site of injection, or is allergic to the medication to be injected
- The patient has the need for more than two facet or nerve block levels at a single treatment session
- The patient's anatomy is such that the facet or nerve root cannot be accessed with a standard straight 22 gauge spinal needle (patients needing a 21/25 gauge coaxial straight and curve needle pair will be excluded)
- Narcotic or pain medication within two hours prior to the procedure

4.1.6 Outcome Measures

For this study, there are both radiographic (accuracy of needle placement) and clinical (pain relief) success criteria. The overall success criteria for the study includes both these factors.

4.1.6.1 Accuracy of Needle Placement

The accuracy of needle placement will be measured on A/P and lateral fluoroscopy as described in Section 9d on page 9 of the protocol (Appendix 1.1). This description is repeated here for convenience. This is the same measurement technique used on the cadaver study completed in September 2001.

At the beginning of the procedure, the attending radiologist will annotate lateral and A/P fluoroscopic images with an arrow to indicate the desired target location. These images will be saved as digital images. When needle placement is complete, lateral and A/P fluoroscopic images will also be saved as digital images. Each pair of images will be imported into Adobe Photoshop (an image-editing software application) and aligned on top of each other. Then, the measuring tool in Photoshop will be used to measure the

distance from the needle tip to the target arrow. The root mean square (RMS) distance from the needle tip to the target arrows will be determined as follows:

RMS distance = square root((A/P distance squared) + (lateral distance squared))

The success criterion is defined as needle placement within 3 mm of the target anatomy.

The failure criterion is defined as needle placement greater than 3 mm from the target anatomy.

4.1.6.2 Pain Relief

For this study, the pain relief measurement instrument has been changed from the McGill Pain Questionnaire (as proposed in the original protocol) to a numerical rating scale. This change was made as it was decided that the McGill Pain Questionnaire (which consists of a series of questions describing the pain) is too difficult to administer for these common interventional procedures.

The numerical rating scale is the current practice for nerve and facet blocks at Georgetown. The patient is asked to identify how much pain they are feeling by choosing a number from 0 (no pain) to 10 (worst pain imaginable) as shown in Figure 2. The success criteria for pain relief in terms of pre-procedural versus post-procedural change will be defined as a reduction in pain (i.e., if the pre-procedure pain was a 6 the post procedure pain must be a 5).
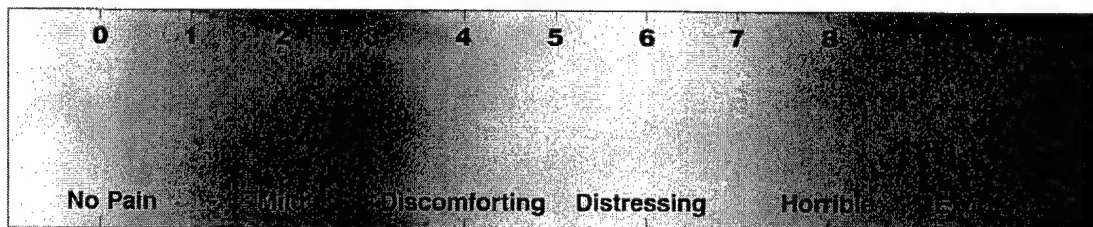
Figure 2: Numerical Pain Scale (0-10)

4.1.7 Case Report Forms

The following forms will be used and are shown in Appendix 4:
- Case Log
- Form 1: Inclusion/Exclusion Criteria
- Form 2: Demographics
- Form 3: Case Report Form
- Form 4: Procedure
- Form 5: Telephone Questionnaire
- Adverse Events

These forms will be used as follows. Once the study begins, every patient who is scheduled for a nerve or facet block is a candidate for the study. When the patient checks

in for their procedure, they will be given a copy of the informed consent and given time to review this document. If the patient agrees to participate and signs the consent form, the physician will review the inclusion/exclusion criteria (Form 1) during the pre-procedure examination. If the patient meets the criteria, they are then eligible for the study.

During the pre-procedure examination, the physician will also complete Form 2: Demographics. As part of this examination, the physician will question the patient as to their pain level, and this information will be recorded on Form 3: Case Report Form. Finally, the physician will verify the type of block (nerve or facet) and the level. This information will be recorded on Form 4: Procedure.

Approximately one week after the procedure, the patients will be contacted by telephone to see how they are doing. This data will be recorded on Form 5: Telephone Questionnaire. Note that patients undergoing these procedures are typically not contacted after the procedure but are instructed to contact the doctor if they experience any abnormal discomfort or symptoms. However, we will follow up by telephone for this study as an additional safety measure.

In these forms, the patient identification will consist of the patient's initials and will be entered on every form. The patient study number will be "FDA IDE*** ###" where IDE*** will be the FDA IDE number and ### will be the patient number from the case log.

For adverse events, the Georgetown University Institutional Review Board form will be used. A copy is provided in Appendix 4.

4.2 Risk analysis

Section 812.25(c) of the Code for Federal Regulations requires that information be provided for the following items:
1. A description and analysis of all increased risks to which subjects will be exposed by the investigation.
2. The manner in which these risks will be minimized.
3. A justification for the investigation.
4. A description of the patient population, including the number, age, sex, and condition.

This information is provided below.

4.2.1.1 Description and Analysis of Increased Risks

Since the procedure will follow standard clinical practice as described in Section 4.1.2, there are no increased risks from the procedure itself. Nerve and facet blocks are minimally invasive procedures, and complications are typically temporary and infrequent. The major complications in any spinal needle procedure are bleeding and infection.

For patients who are randomized to the robotically assisted needle placement group, there are potentially increased risks from the use of the robot, although these are considered to be extremely minimal (in fact the robot may minimize overall risk by providing more precise control of the needle). While the robot has been extensively tested, it may malfunction and drive the needle in an unintended fashion.

In the literature, for lumbar facet blocks, it has been noted that complications are usually temporary and infrequent (Gray page 474). The problem most often cited is a transient exacerbation in pain (about 2% incidence) lasting (in rare cases) as long as 6 weeks to 8 months. Spinal anesthesia has occurred after facet joint injection. Several repots of chemical meningitis after lumbar facet block have been published. Both of these complications are thought to have occurred after inadvertent dural puncture. Paraspinal infections have also been reported after facet injections. Facet capsule rupture also occurs, especially when more than 2.0 mL of injectate is used.

In the literature, for lumbar nerve blocks, it has been noted that complications are uncommon (Waldman page 421). Side effects and complications noted by Waldman include inadvertent dural and subdural puncture, intraveneous placement of the needle, and infections.

4.2.1.2 Manner in Which Risks Will be Minimized

The risks associated with the robotic device have been minimized as follows:

   1. A relatively safe minimally invasive procedure was chosen as the first spinal procedure for using the robot.

   2. The robot has been designed, manufactured, and bench tested with quality in mind as described in Section 5.

   3. A cadaver study has been completed in the interventional suite environment (the same environment as used for clinical care) as described in Section 3.1 and Appendix 2.1.

   4. The physician will remain in direct control of the robotic device at all times, and can discontinue its use at any time.

4.2.1.3 Justification for the Investigation

The anticipated benefit of the robotic device is that it may help the physician place the needle more precisely and efficiently, which may improve the outcome of the procedure. There is a large class of minimally invasive interventional procedures, in the spine and elsewhere, that might benefit from more precision and efficient placement of instruments as provided by robotic devices like the one described here. However, clinical experience with these devices is limited and the actual benefit of using such a system has not been proven. Therefore, clinical studies like the one proposed here are needed to investigate if these robotic devices can improve patient care.

4.2.1.4 Patient Population

The total number of subjects that we hope to enroll in this feasibility study is 100 (50 using the robotic device and a comparison group of 50 without the robotic device). The patients will be drawn from the clinical practice of Dr. Watson. The mix of patients

varies, but typical patients are from 25 to 70 years old and male or female. The estimated percentage of patients undergoing facet block is 50% and the estimated percentage of patients undergoing nerve block is 50%. The physical condition of the patients vary in that some are in good health except for back pain while some are in poor health due to cancer or other disease.

4.3 Description of the Device

A picture of the robotic device is shown in Figure 3. The device consists of:
1) A mechanical arm that can be positioned at any location above the patient's spine.
2) A touch screen and joystick through which the operator can control the device.
3) A mounting base that attaches the device to the interventional table.
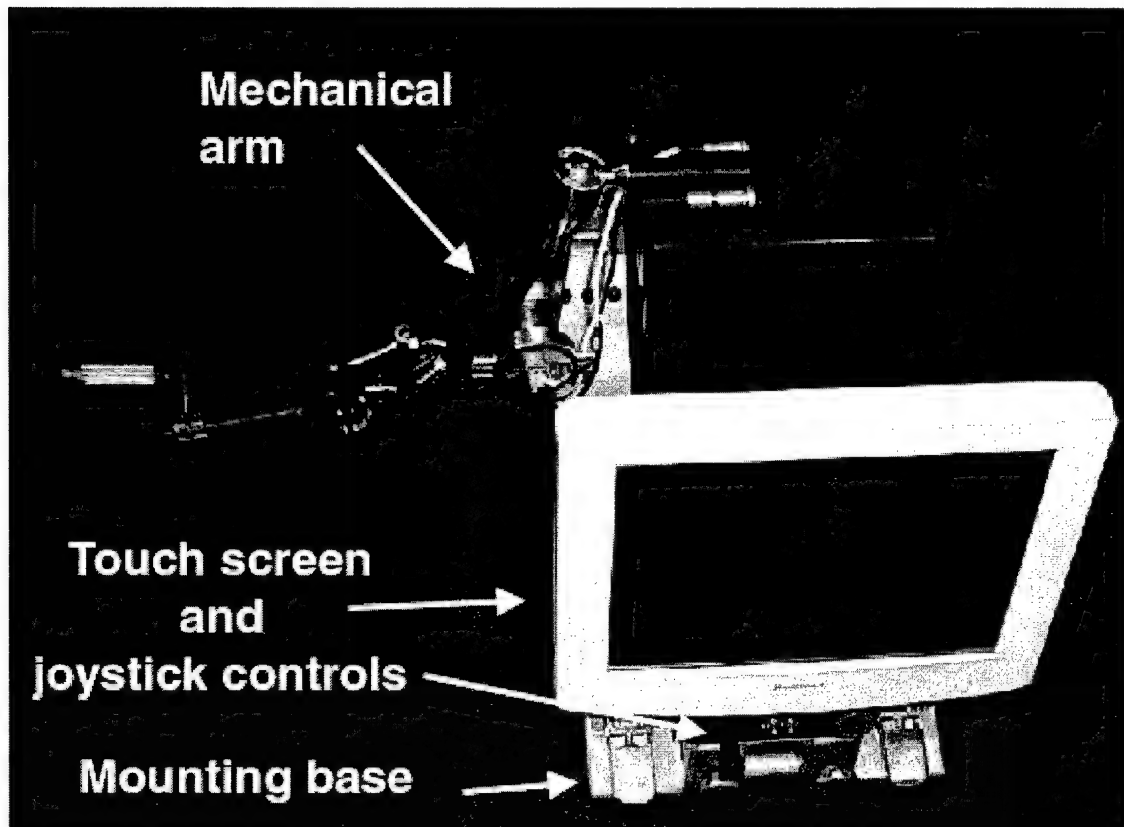
Figure 3: Robotic device showing mechanical arm and joystick control

For this study, the robot will be mounted on the interventional table as shown in Figure 4. This figure shows bench testing of the robot at Georgetown using a cantaloupe.

Based on the cadaver study, a typical scenario for needle placement is as follows. The passive arm is unlocked and the needle tip is placed within a few centimeters of the skin entry point. The robot is then set to translational mode by selecting this mode on the touch screen. Using the joystick, the physician moves the tip of the needle to the skin entry point while monitoring the position of the robot by direct vision. The robot is then set to rotational mode by selecting this mode on the touch screen. Using the joystick once again, the physician orients the needle to point towards the target point while monitoring

the orientation using A/P fluoroscopy. When the physician is satisfied that the needle is pointing toward the target, the robot is then set to needle drive mode by selecting this mode on the touch screen. Using the joystick once again, the physician can drive the needle toward the target while monitoring the needle depth and trajectory using lateral fluoroscopy. The benefit of the robot is that it is a precise and stable mechanical arm for orienting and driving the needle towards the target anatomy. If there are any problems with the robot at any point during the procedure, the physician can stop using the robot and revert to the standard manual technique of placing the needle by hand.
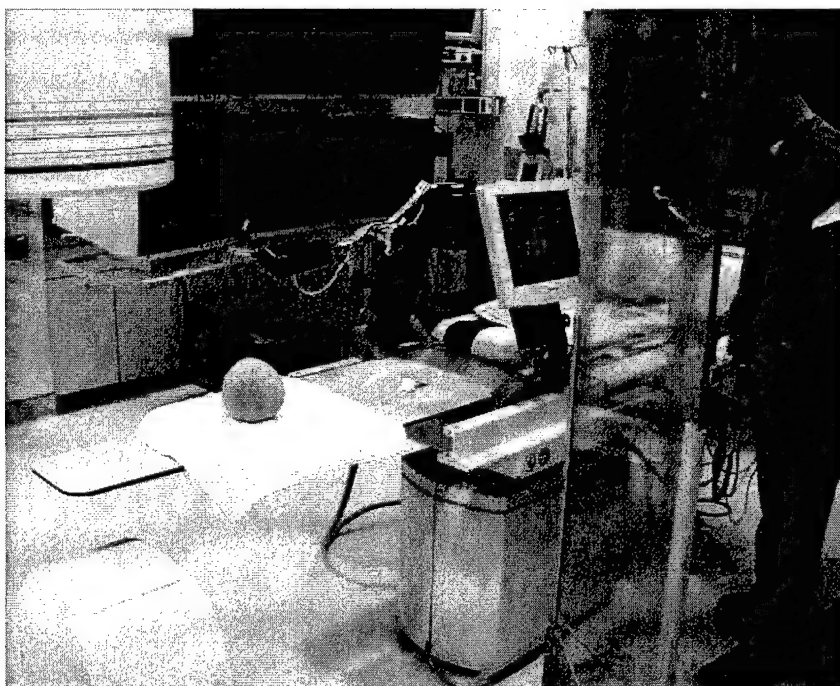
Figure 4: Robot arm hardware mounted on fluoroscopy table at Georgetown

**Figure 5: Cadaver study showing joystick control of robot and
monitoring of needle placement on fluoroscopy monitors**

4.4 Monitoring procedures

As described in Section 9c on page 8 of the Protocol (Appendix 1.1), a Data Monitoring and Patient Safety Board has been formed to review the results of the first 20 patients (10 with, 10 without the device). This Board consists of William Lauerman, MD, an orthopedic spine surgeon at Georgetown, and Fraser Henderson, MD, a spinal neurosurgeon at Georgetown. Both of these physicians refer patients to Dr. Watson for spinal nerve blocks.

After the first 20 patients, the results will be compiled and presented to the Data Monitoring and Patient Safety Board for review of safety and efficacy. The results will consist of the average accuracy with and without the robotic device, the change in pain scores, and any complications observed. This Board will have the power to stop the study or suggest modifications.

5 Manufacturing Process

The robotic device was designed and manufactured in the Urology Robotics Laboratory (URobotics) of the Urology Department at Johns Hopkins Medical Institutions under the direction of Dan Stoianovici, PhD. As noted earlier, Dr. Stoianovici has been funded under Dr. Cleary's Army project through a subcontract.

The URobotics program has extensive dedicated facilities (1600 square feet) including offices, laboratory space, and a machine shop (600 square feet) fully equipped for robotic

device design and manufacturing. The URobotics machine shop (Figure 6) includes state-of-the-art machine tools and equipment such as:

- Vertical machining center HAAS VF-1
- CNC turning center HAAS SL-20
- Vertical turret milling machine, CHEVALIER FM-3VK
- Gear head lathe JET GH-1340A with ANILAM digital readout
- Vertical band saw VICTOR DMC-4 with blade welder
- MSC-951240 drill press
- Square Wave TIG-255 welding machine by Lincoln Electronic
- Vulcan A-550 heat treatment furnace with automatic controls
- Complete other auxiliary equipment including tooling

Figure 6: The URobotics machine shop: milling machine and lathe (left), HAAS VF-1 vertical machining center (center), and HAAS SL-20 CNC turning center (right)

The URobotics program has a history of designing, building, and clinically applying robotic devices for minimally invasive procedures. Strict attention to quality is part of the entire manufacturing and assembly process. Modules are tested individually and the final product is tested extensively when complete.

The robotic device was completed and passed final tests at Johns Hopkins in August 2001. Since then, we have tested the device extensively at Georgetown, both in the laboratory and in the interventional suite. We have operated the device throughout a full working day to verify the robustness of the system. We have also completed a cadaver study in the interventional suite as summarized in Section 3.1 and detailed in Appendix 2.1. In summary, both the investigator-sponsor Dr. Cleary and the clinical investigator Dr. Watson feel confident that the device is ready for a clinical trial.

6 Investigator Agreements & Name and Address

Vance Watson, MD, is the clinical investigator for this project. Dr. Watson is an interventional neuroradiologist in the Department of Radiology at Georgetown University Medical Center. Dr. Watson has been collaborating with Dr. Cleary since the inception of this project two years ago. He is listed as the principal investigator on the protocol and

consent forms that have been approved by the Georgetown IRB and the Army Human Subjects Board.

A signed agreement letter from Dr. Watson is included in Appendix 3 along with his curriculum vitae. Dr. Watson is uniquely qualified to conduct this investigation based on his expertise in interventional spine procedures and his collaboration with Dr. Cleary over the last two years.

The address for Dr. Watson is:
Vance Watson, MD
Department of Radiology
MedStar Georgetown University Medical Center
3800 Reservoir Road
Washington, DC 20007
Phone: (202) 784-1399
Fax: (202) 784-4896
Email: vancewatson@yahoo.com

7 Certification

As sponsor/investigator for this study, I, Kevin Cleary, certify that all investigators have signed the agreement, that the list of investigators includes all investigators participating in the study, and that new investigators will sign the agreement before being added to the study.

_____   _____
Kevin Cleary, PhD   Date

8 IRBs

The research plan described here has been approved by the Georgetown IRB and the Army Human Subjects Board. A copy of the approval letter from Georgetown is given in Appendix 1.3 and a copy of the contract modification from the Army showing approval is given in Appendix 1.4. The names, addresses, and chairpersons of these two boards are listed below.

Georgetown University Medical Center Institutional Review Board
Protocol and consent approved: 2 February 2001 (Appendix 1.3)
Chairperson and address:
Chairperson: Willard Barnes, MD
Executive Officer: Elisabeth Crigler
Telephone: (202) 687-1506
NE105 Medical Dental Building
Georgetown University Hospital
3800 Reservoir Road
Washington, DC 20007

U.S. Army Office of Regulatory Compliance and Quality
Human Subjects Protection Board
Protocol and consent approved: 2 March 2001 (Appendix 1.4)
Chairperson and address:
     Cognizant official: Louise Pascal
     Telephone: (301) 619-2607
     Commanding General
     US Army Medical Research and Materiel Command
     ATTN: MCMR-RCQ-HR/Louise Pascal
     504 Scott Street
     Fort Detrick MD 21702-5012

9 Other Institutions

The only other institution involved in this study is The Johns Hopkins Medical
Institutions. The device is manufactured by the Urology Robotics Laboratory at Johns
Hopkins as described in Section 4.

In future studies, it is anticipated that the device may be used in clinical studies at Johns
Hopkins and at the National Institutes of Health. As certified in Section 7, new
investigators will sign the agreement before being added to the study.

10 Amount Charged for the Device

No fees will be charged for the use of the device. The development of the device has been
funded under the Army study as noted earlier.

11 Claim for Categorical Exclusion

Devices shipped under the investigational device exemption are intended to be used for
clinical studies in which waste will be controlled or the amount of waste expected to
enter the environment may reasonably be expected to be nontoxic. The robotic device
described here falls under this category.

12 Device Labeling

The device will be labeled in accordance with Section 812.5 of the IDE regulations. The
label will be placed at a prominent location on the device and read:

Medical Robotic Device

Designed and Manufactured By:
URobotics Laboratory
Johns Hopkins Medical Institutions

CAUTION: Investigational device. Limited by Federal
(or United States) law to investigational use.

13 Informed Consent Forms

The informed consent form for the project is attached in Appendix 1.2. This consent form
has been approved by the Georgetown IRB and the Army Human Subjects Board.

14 References

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Waldman, WB Saunders Company, 446-483.

10.6 Medical Simulation Tutorial

Introductory presentation begins on the next page and is 11 pages long.

Medical Simulation Tutorial
SPIE Medical Imaging 2001

Kevin Cleary, Ph.D.

Imaging Science and Information Systems (ISIS) Center,
Radiology Department,
Georgetown University Medical Center

Acknowledgement

ISIS Center, Radiology   Georgetown University   Slide 2

Faculty

- Jianchao Zeng, PhD
  - ISIS Center, Georgetown University
- Gerry Higgins, PhD
  - Washington Area Computer Aided Surgery Society
- Chris Kaufmann, MD
  Alan Liu, PhD
  - National Capitol Area Medical Simulation Center of The Uniformed Services University of the Health Sciences

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Schedule

- 1:30 – 2:00   Cleary   Introduction
- 2:00 – 2:30   Zeng   Components
- 2:30 – 3:00   Higgins   Historical Review
- 3:00 – 3:30   Break   Demonstration
- 3:30 – 4:00   Kaufmann Clinical Needs
- 4:00 – 4:30   Liu   Simulation Center
- 4:30 – 5:00   Higgins   Evaluation

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Definition

- Simulator – interactive virtual environment used to improve human performance

- Not necessarily computer-based (but personal computer-based systems are focus here – "desktop medical simulation")

Uses of Medical Simulators

- Medical education / training
- Scientific analysis (biomechanical studies, device design and testing)
- Pre-treatment planning

Types of Medical Simulators

- <u>Plastic mannequins</u> - Physical models for practicing procedures such as intubation and IV placement.

- <u>Computer-based mannequins</u> - Used for training and testing skills in anesthesiology and related applications.

- <u>Virtual environment (VE) simulators</u> - Contain a computer graphics model and provide an immersive experience.

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Plastic Mannequin

Patient Simulators
(MedSim)

- Plastic mannequin
- Computerized sounds and physiology
- Skill assessment
- Trauma training applications

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Computer-based Mannequin

CathSim Needle Insertion
Simulator
(Immersion Medical)

- Tactile interface
- Physics-based simulation
- Skill assessment
- Patient case studies
- 3D graphics
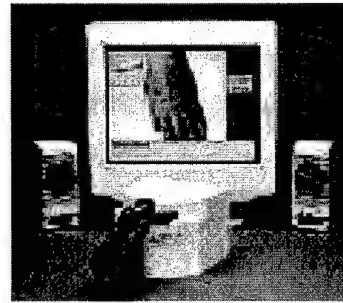
Virtual Environment Simulator

Virtual Surgery Simulator -
Suturing Skills
(Boston Dynamics, Inc.)

- Mirror-based workbench
- Stereoscopic glasses
- Audio
- PHANToM interface
- Graphics computer

Example Medical Simulator

- Spine biopsy simulator
- Common medical procedure
- Interventional procedures are well-suited to simulation
- Joint effort
  - Georgetown University
  - Korean Advanced Institute of Science and Technology (KAIST)

Haptic System Configuration
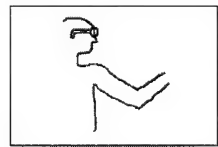
Simulator GUI: Initial Screen
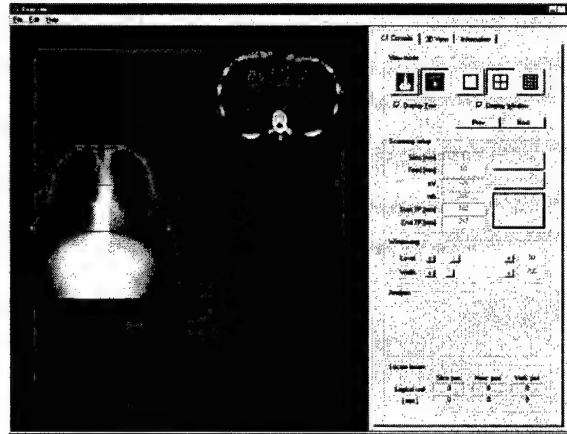
GUI developed by the Image Systems Lab, Dept of Electrical Engineering,
KAIST, Korea, Directed by Dr. Jong Beom Ra

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Simulator GUI: Axial Slices
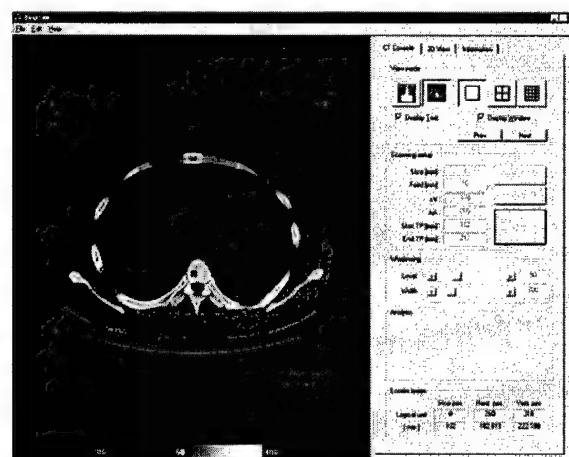
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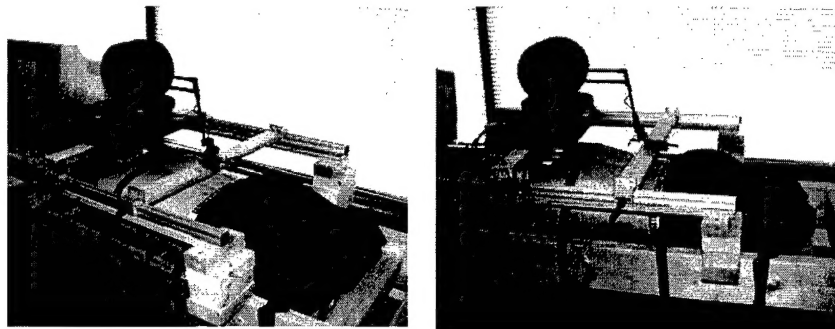
Simulator GUI: 3-D Rendering
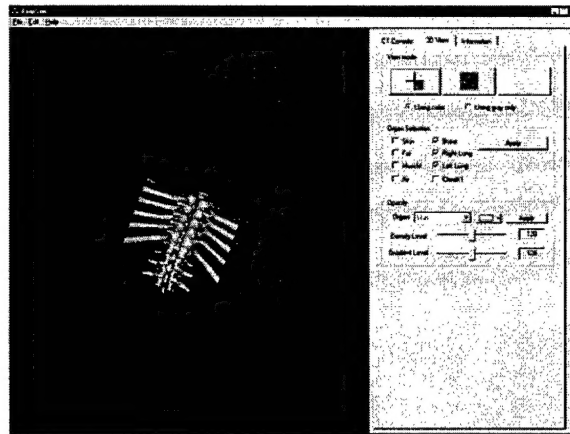
Physical Interface

Anatomical Modeling

- Goal: accurate real-time replication of interaction between an instrument & soft tissue
- 3 classes of anatomical models
  - Non-deformable
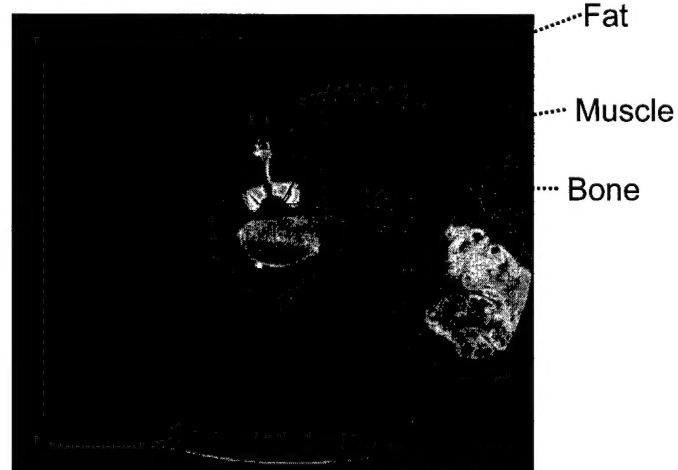 - Deformable surface-based
  - Deformable volume-based

Force-feedback Methods

- Tissue/force profile scheme
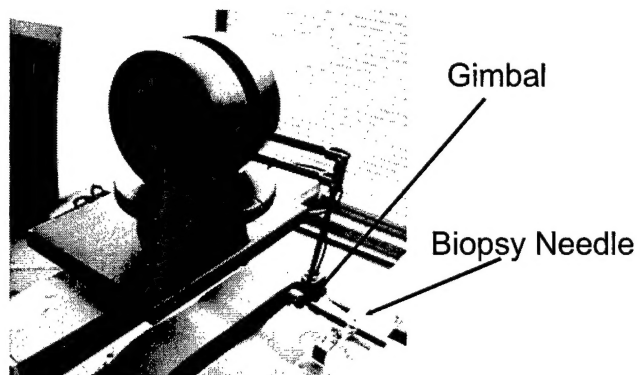- Surface rendered modeling
- Finite element analysis

Spine Biopsy Simulator Model

- Heuristic model - 3 regions:
    1. Initial needle puncture (fat to muscle)
    2. Homogeneous force (muscle)
    3. Hard stop (bony structure)

Heuristic Model

Fat

Muscle

Bone

PHANToM Haptic Device

Gimbal

Biopsy Needle

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